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(12) **United States Patent**
**Malek**

(10) **Patent No.: US 9,095,420 B2**
(45) **Date of Patent: Aug. 4, 2015**

(54) **ENDOVASCULAR STENT**

(75) Inventor: **Adel M. Malek**, Weston, MA (US)

(73) Assignee: **TUFTS MEDICAL CENTER, INC.**, Boston, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 58 days.

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(22) PCT Filed: **Jan. 18, 2012**

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PCT Pub. Date: **Aug. 2, 2012**

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**Related U.S. Application Data**

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(51) **Int. Cl.**

| | |
|---|---|
| ***A61F 2/06*** | (2013.01) |
| ***A61F 2/86*** | (2013.01) |
| ***A61F 2/88*** | (2006.01) |
| ***A61F 2/89*** | (2013.01) |
| *A61F 2/852* | (2013.01) |
| *A61F 2/82* | (2013.01) |

(52) **U.S. Cl.**
CPC ... ***A61F 2/06*** (2013.01); ***A61F 2/86*** (2013.01); ***A61F 2/88*** (2013.01); ***A61F 2/89*** (2013.01); *A61F 2/852* (2013.01); *A61F 2002/067* (2013.01); *A61F 2002/068* (2013.01); *A61F 2002/823* (2013.01)

(58) **Field of Classification Search**
CPC .................................... A61F 2/06; A61F 2/08
USPC ................................................. 623/1.1–1.48
See application file for complete search history.

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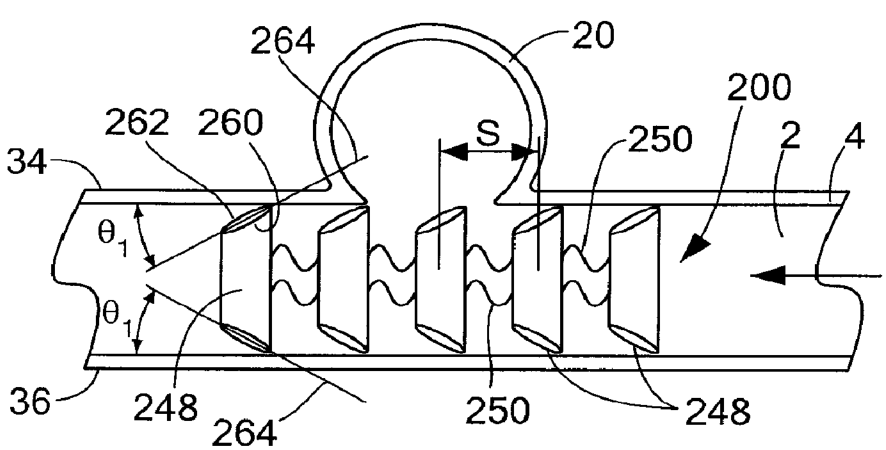
*Primary Examiner* — Suzette J Gherbi
(74) *Attorney, Agent, or Firm* — Occhiuti & Rohlicek LLP

(57) **ABSTRACT**

An intravascular stent is provided for treatment of an aneurysm in a vessel wall of a cranial blood vessel. The stent includes at least one a flow-shaping member including a flow-facing surface that protrudes from an inner surface of the stent and is configured to control at least one of the direction, velocity and secondary flow characteristics of the blood flow within the aneurysm.

**31 Claims, 18 Drawing Sheets**



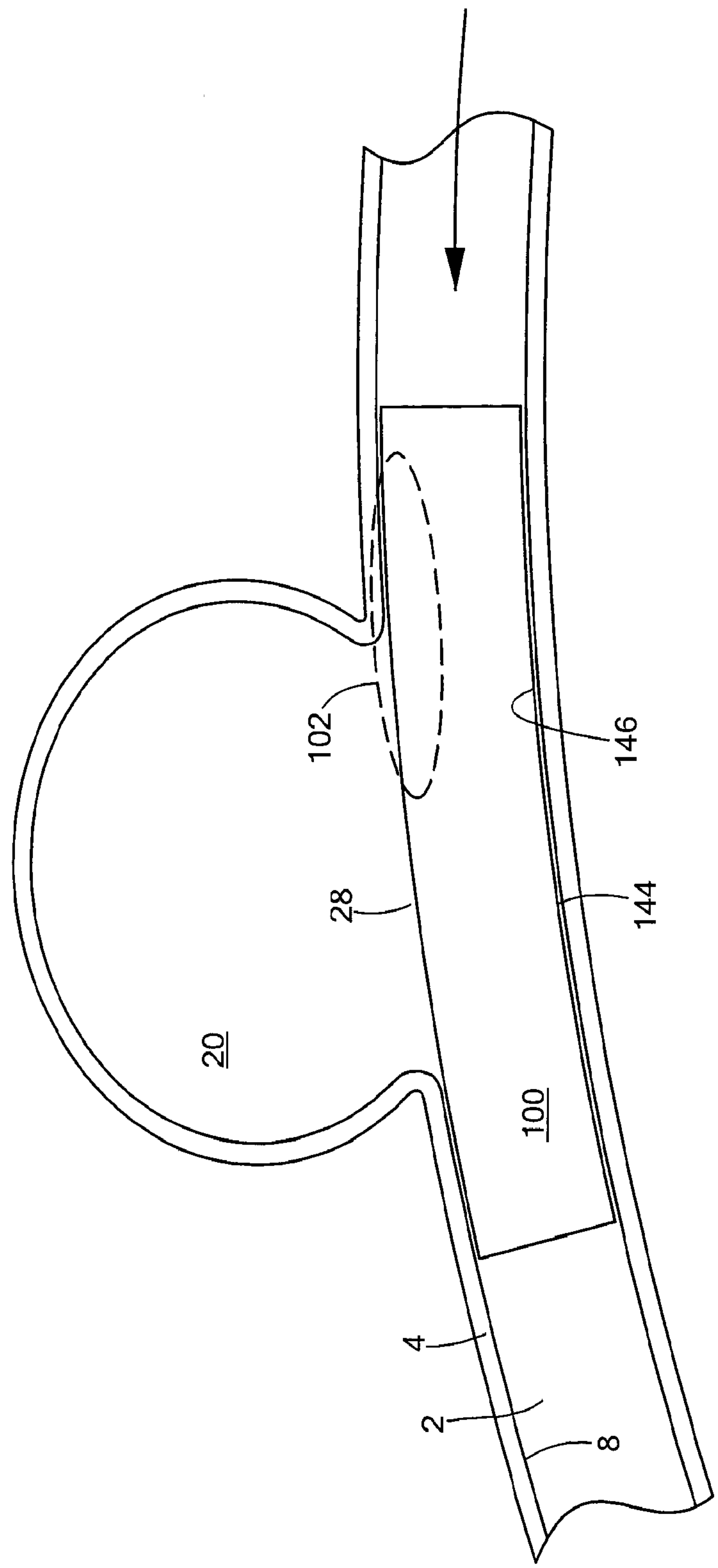



FIG. 1

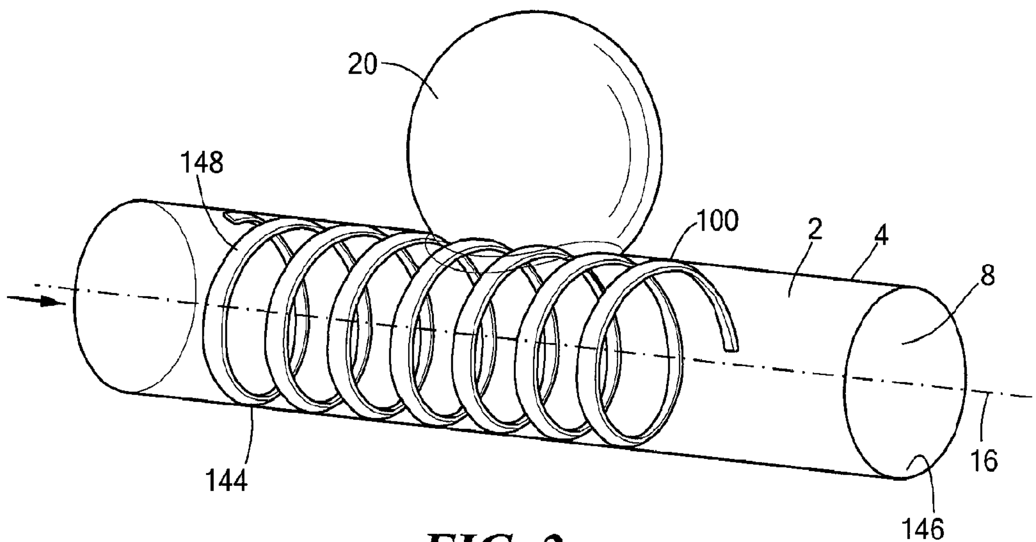



FIG. 2a

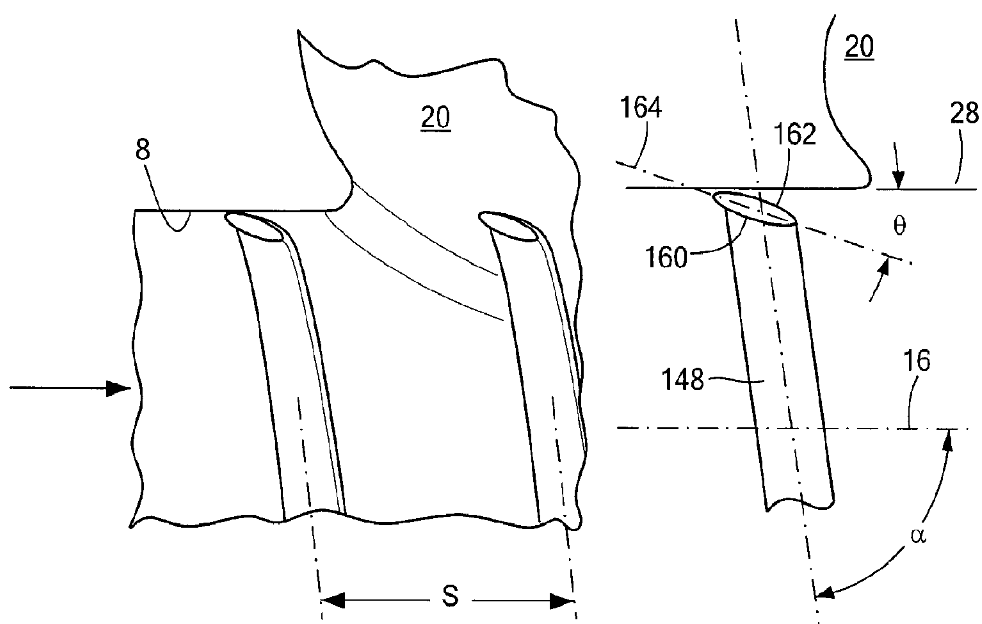



FIG. 2b

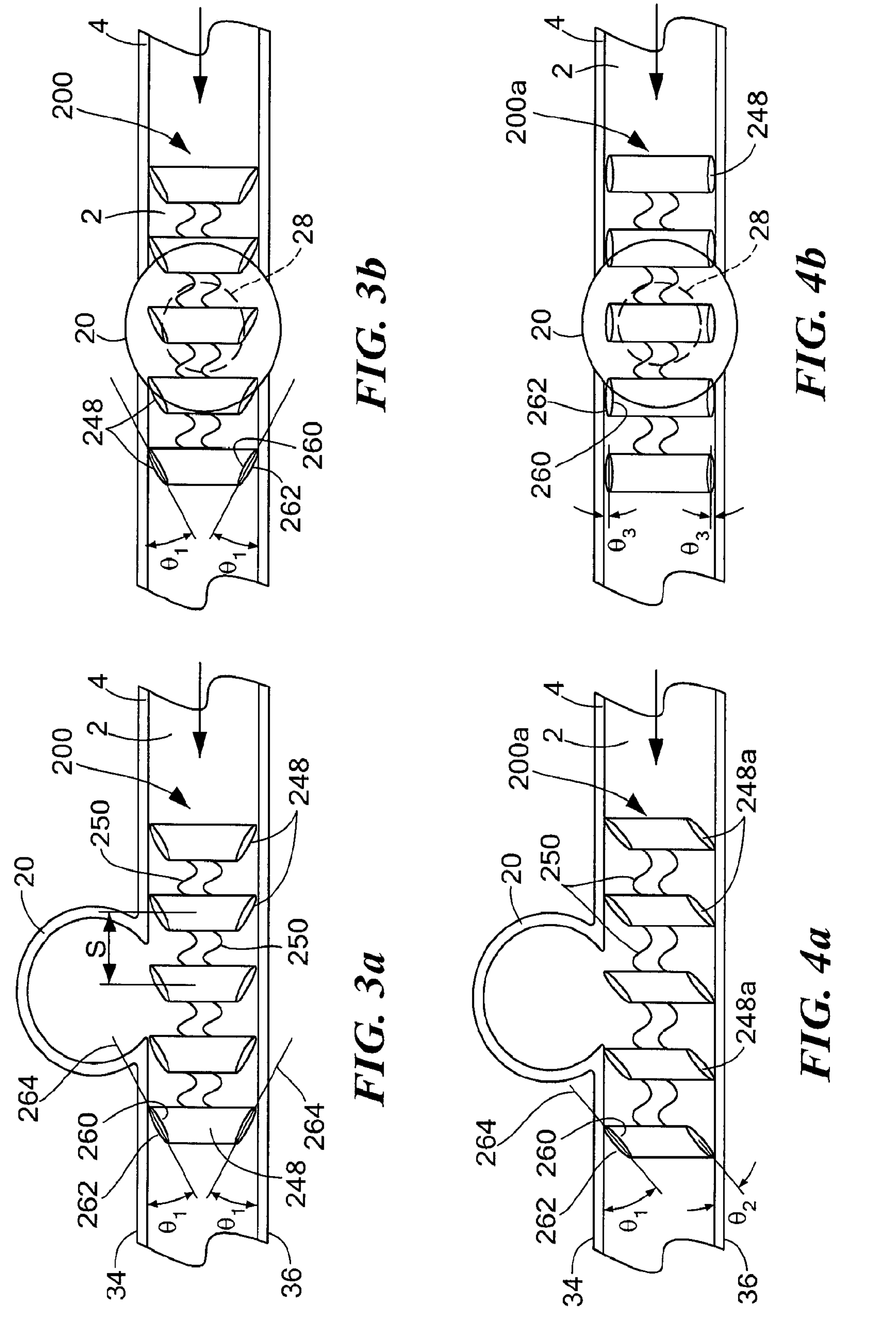



FIG. 3b

FIG. 4b

FIG. 3a

FIG. 4a

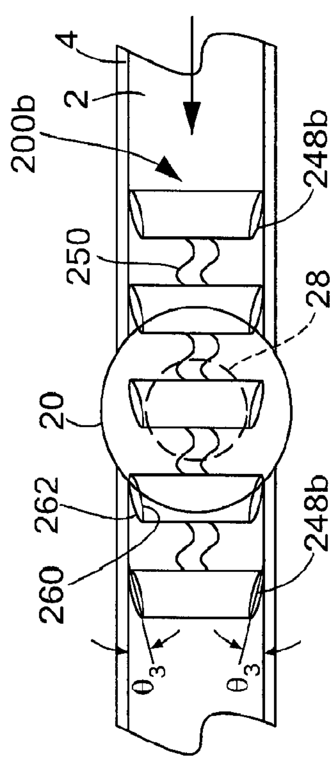



*FIG. 5b*

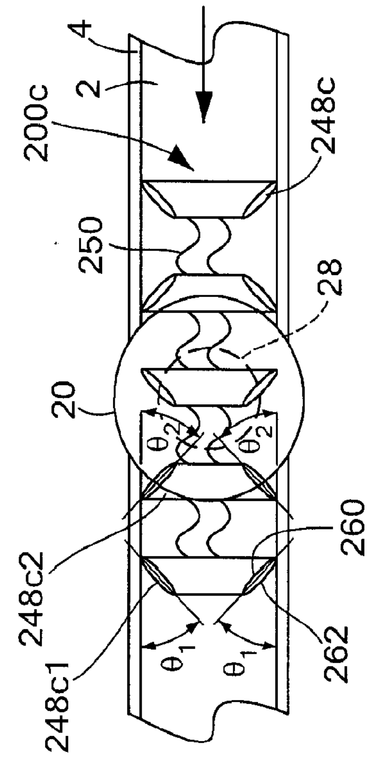



*FIG. 6b*

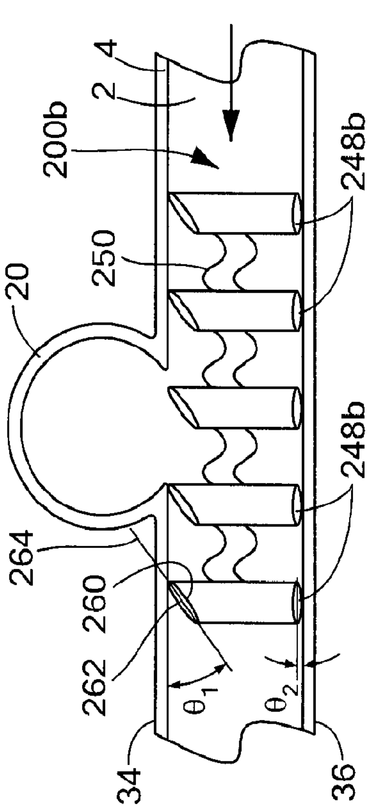



*FIG. 5a*

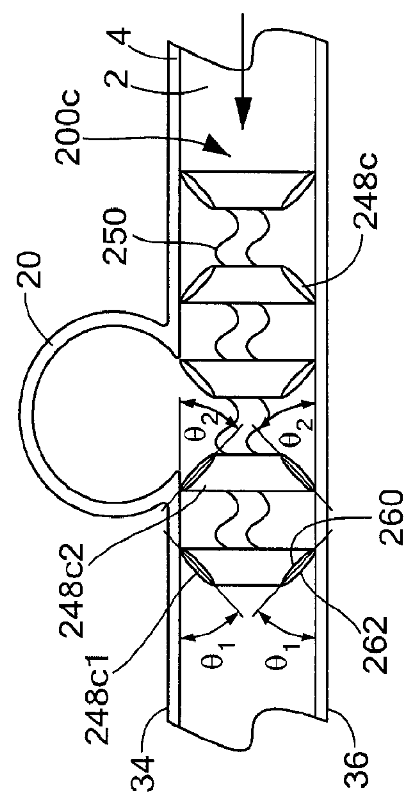



*FIG. 6a*

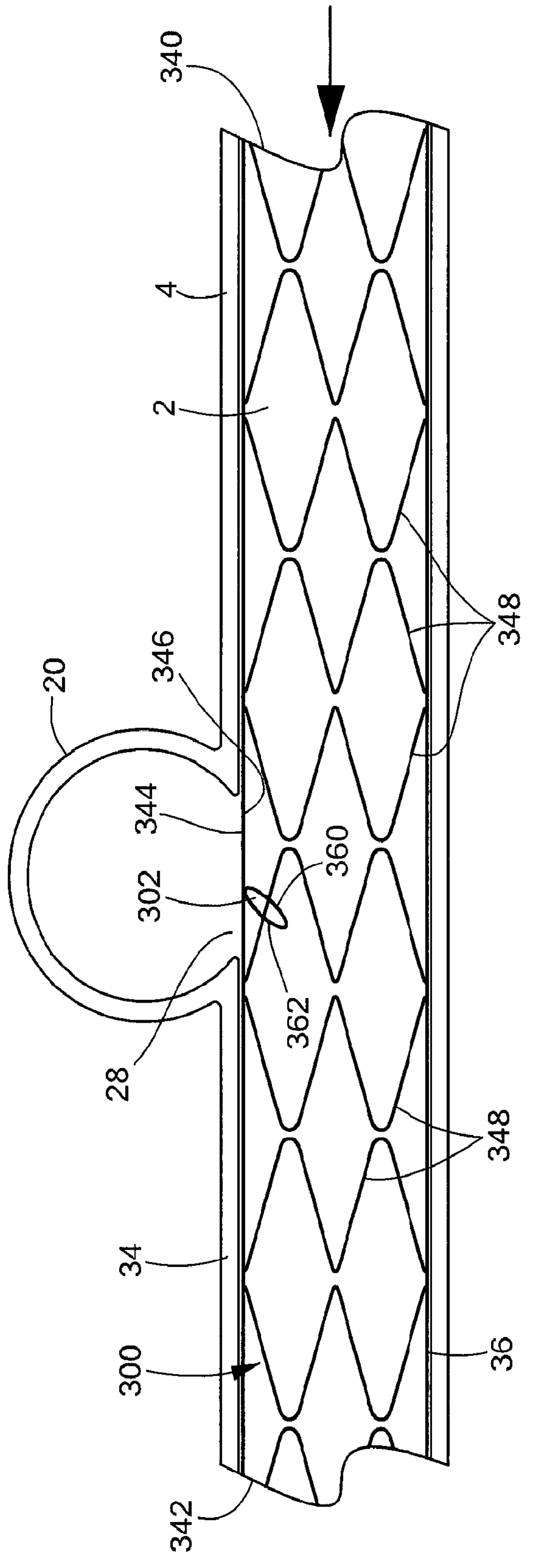



FIG. 7a

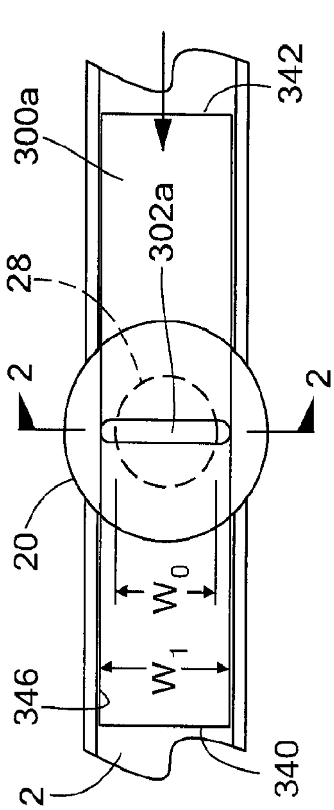



FIG. 7c

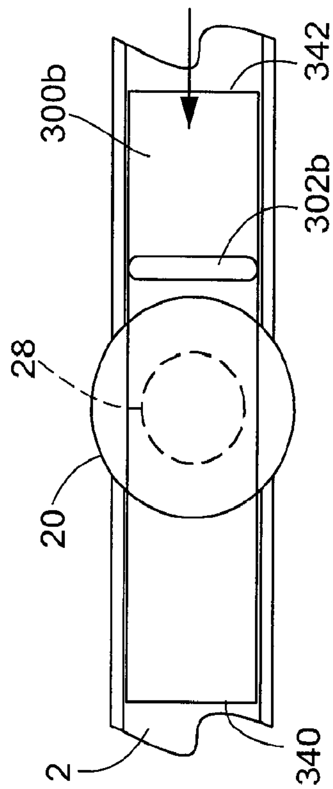



FIG. 8b

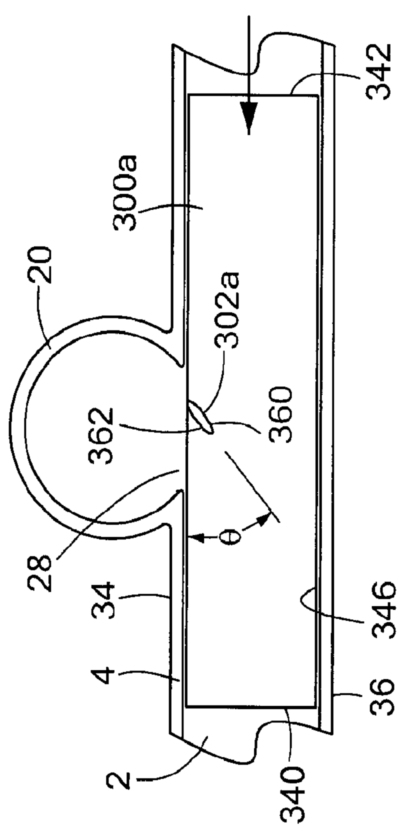



FIG. 7b

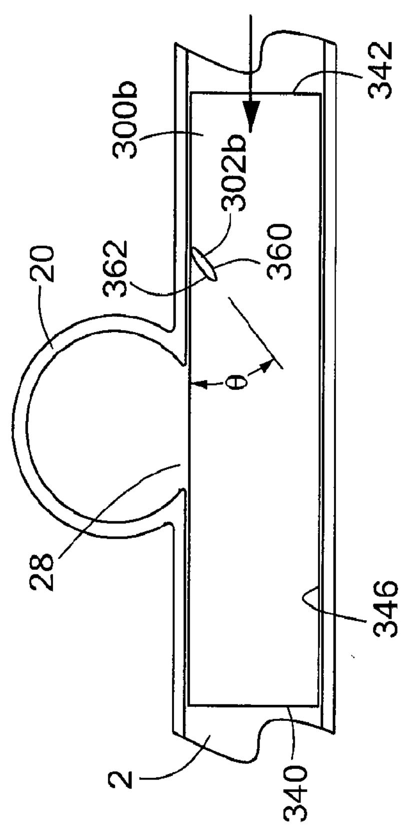



FIG. 8a

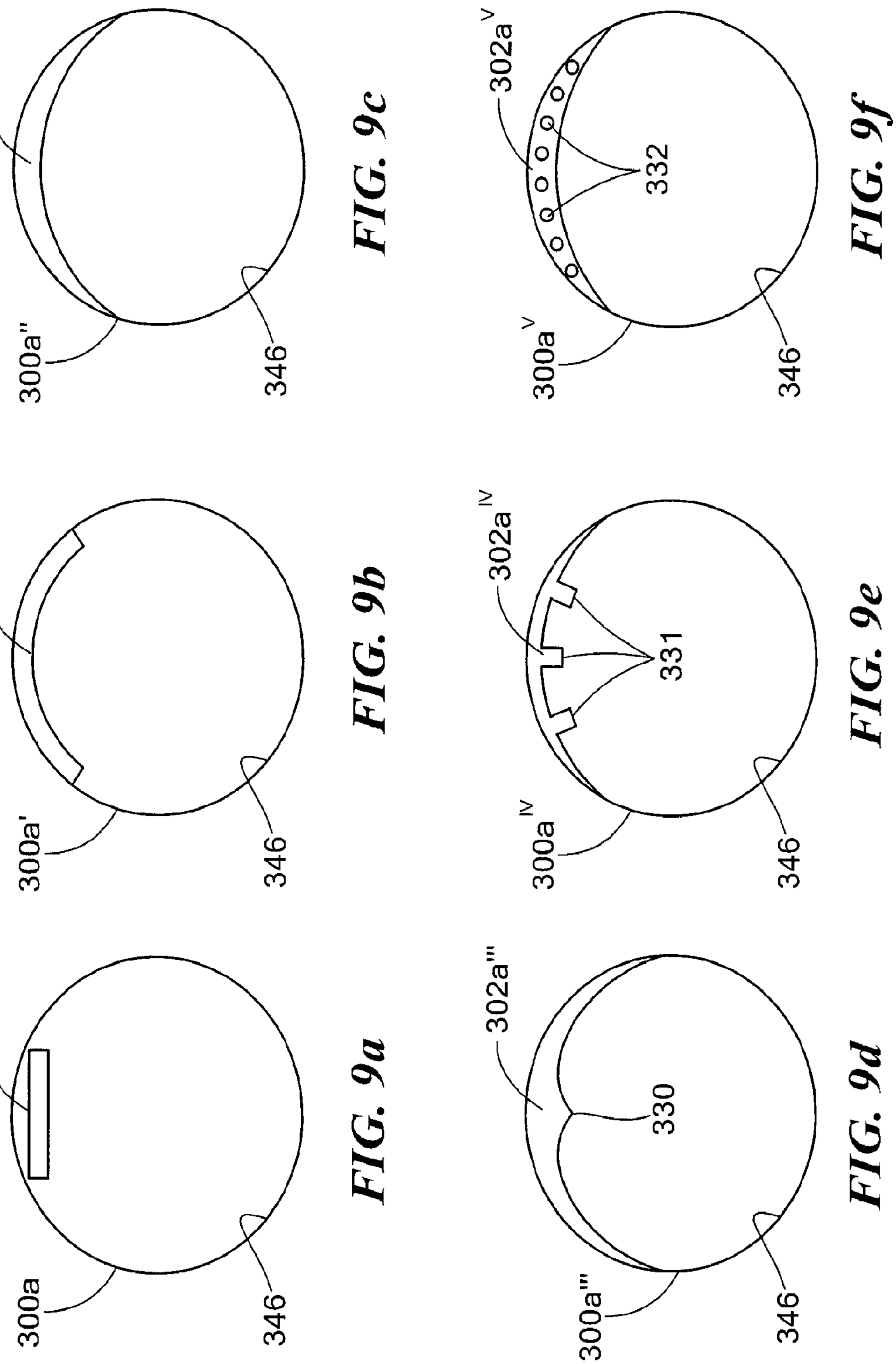



FIG. 9a

FIG. 9b

FIG. 9c

FIG. 9d

FIG. 9e

FIG. 9f

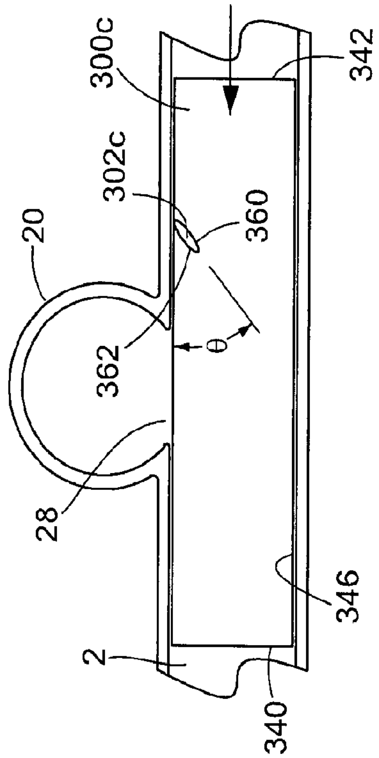



FIG. 10a

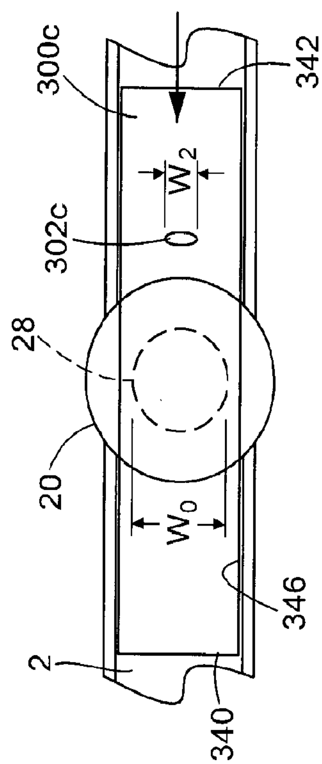



FIG. 10b

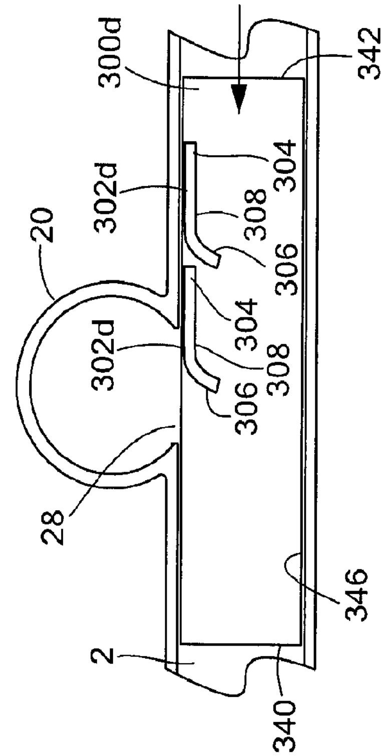



FIG. 11a

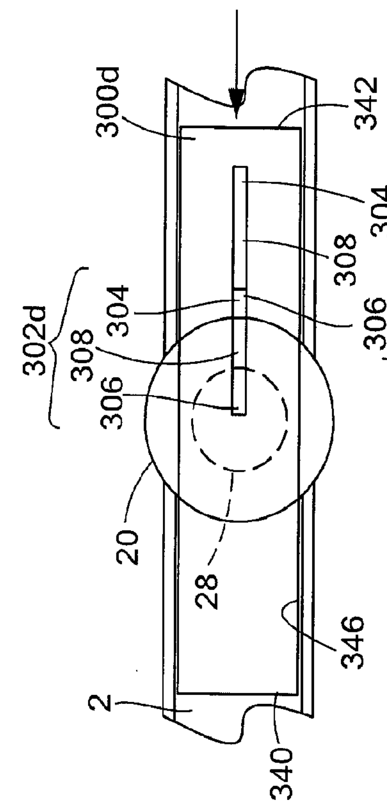



FIG. 11b

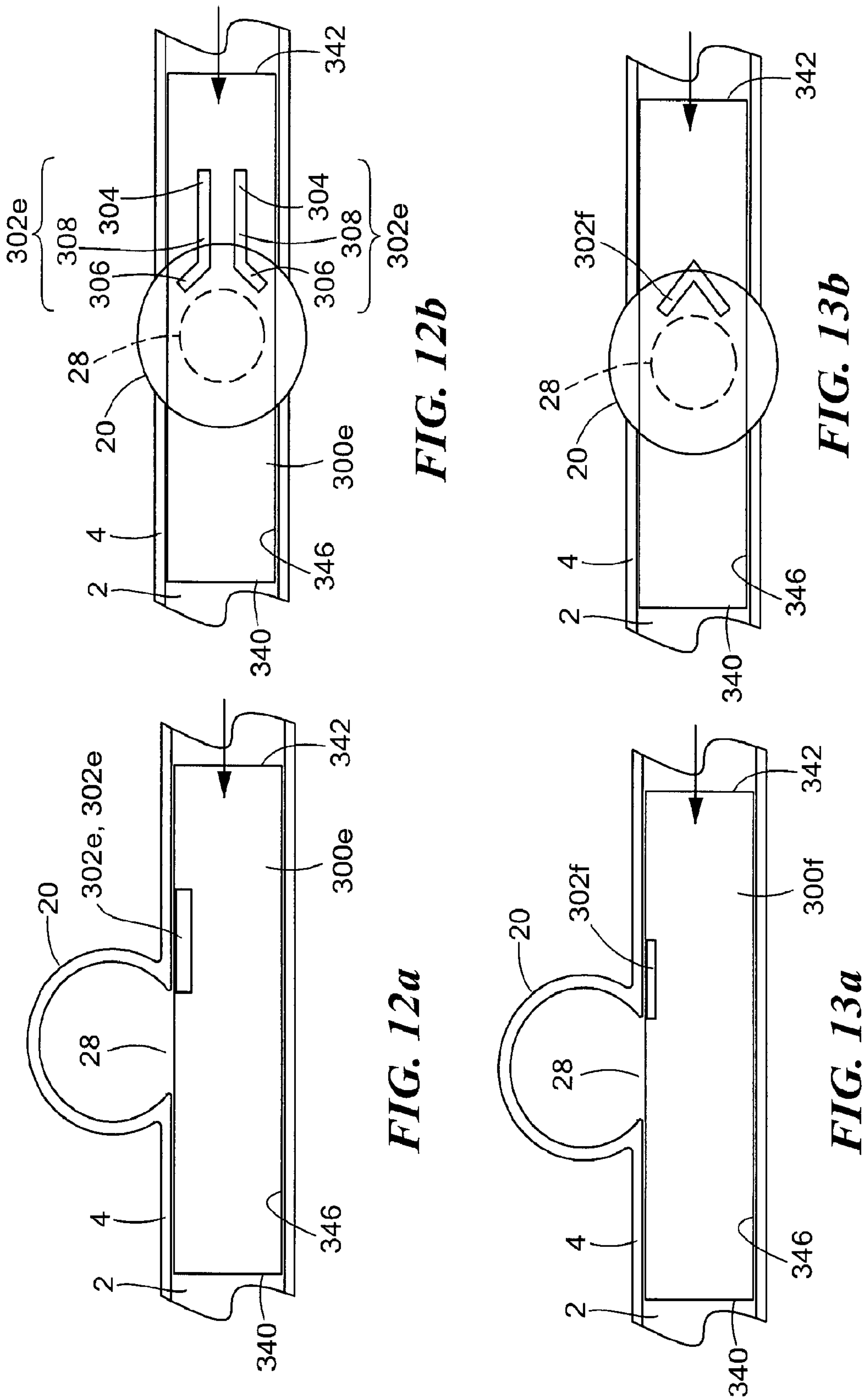



FIG. 12b

FIG. 13b

FIG. 12a

FIG. 13a

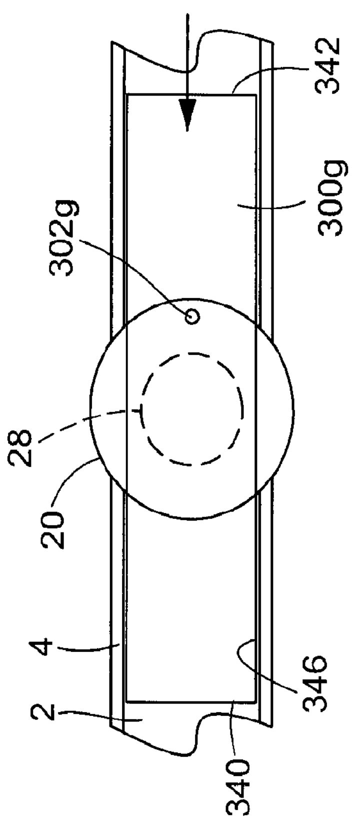



FIG. 14b

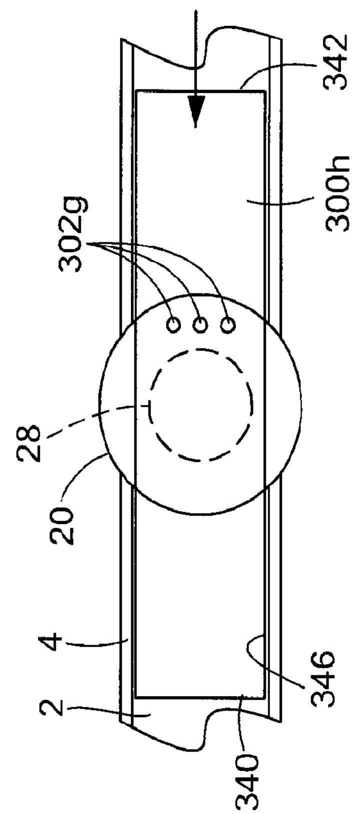



FIG. 15b

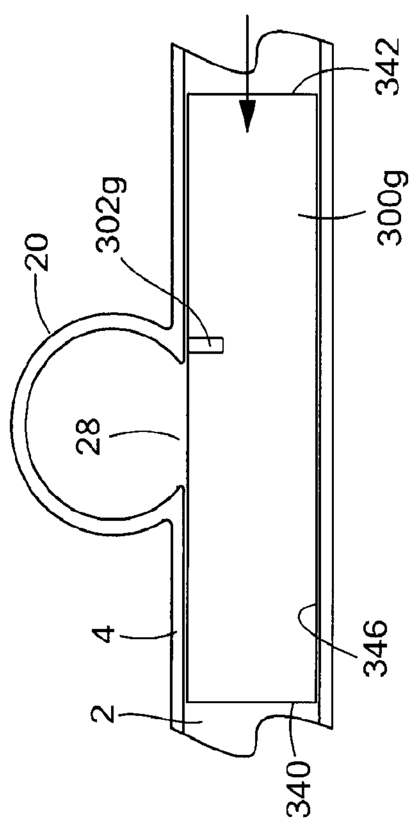



FIG. 14a

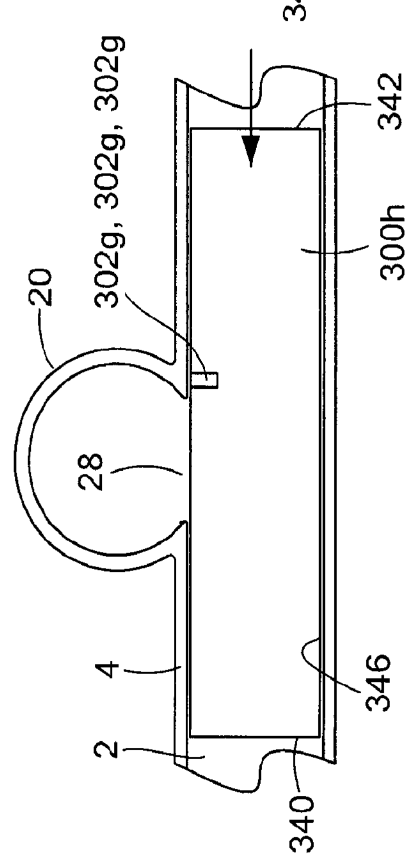



FIG. 15a

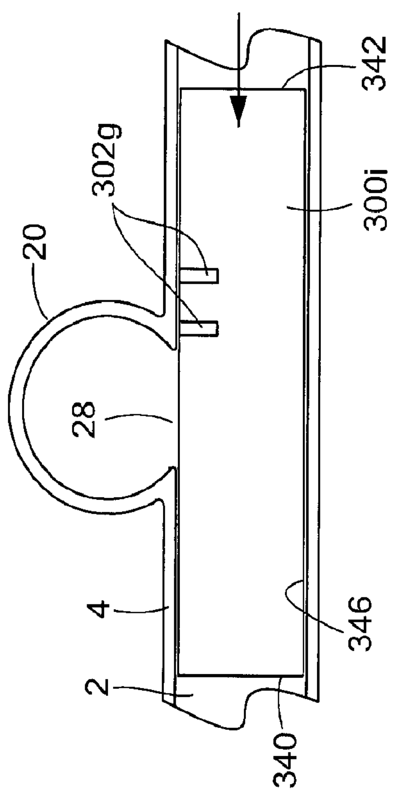



FIG. 16a

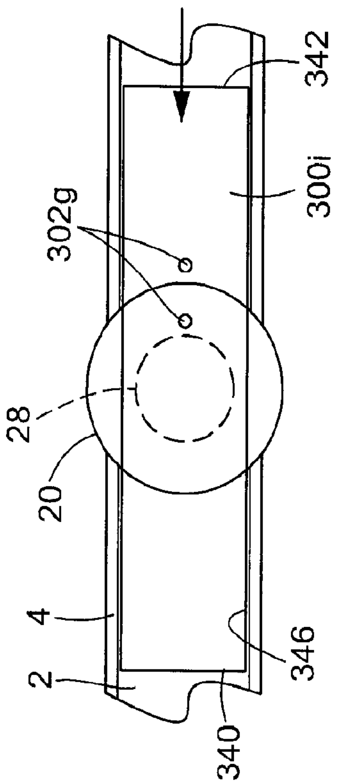



FIG. 16b

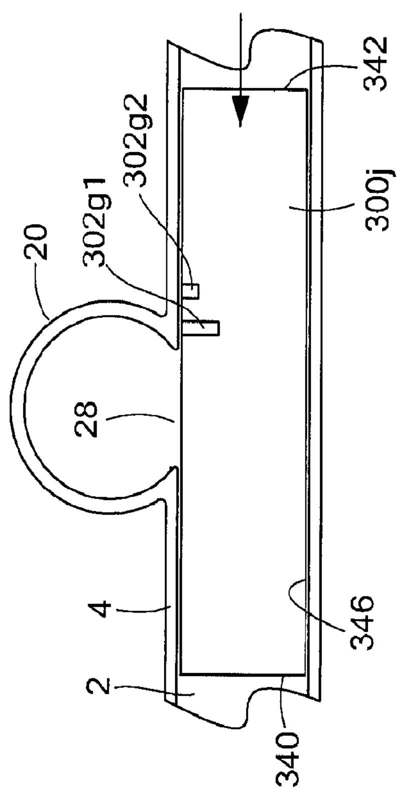



FIG. 17a

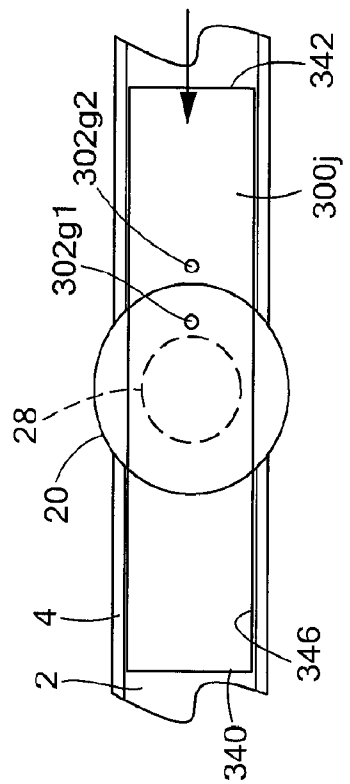



FIG. 17b

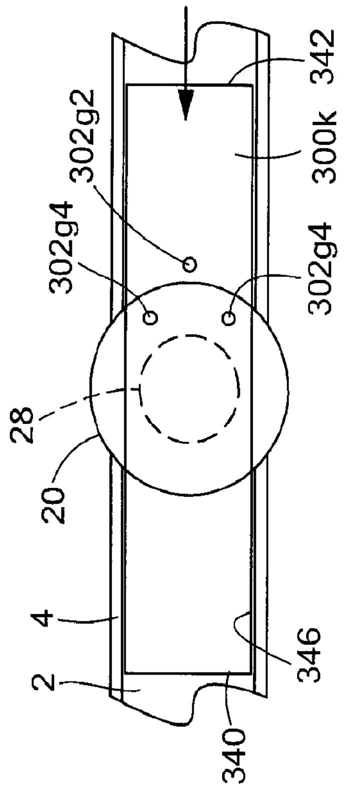



FIG. 18b

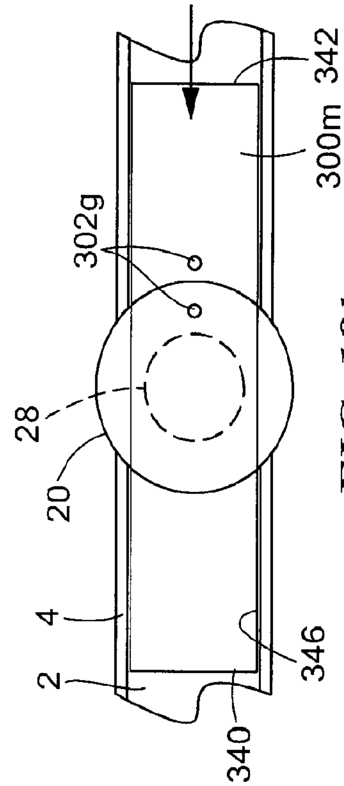



FIG. 19b

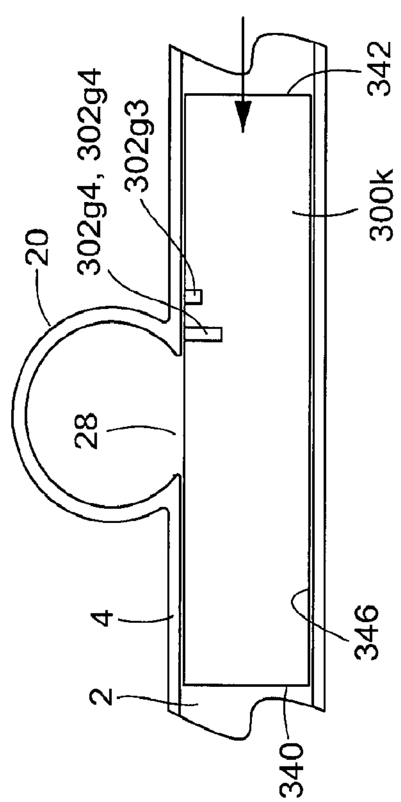



FIG. 18a

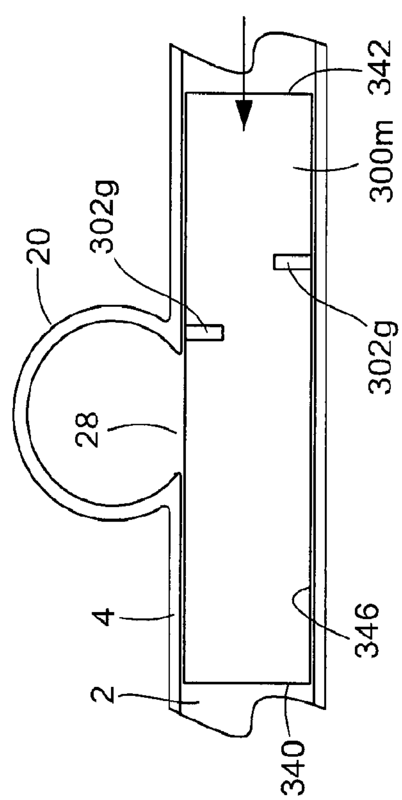



FIG. 19a

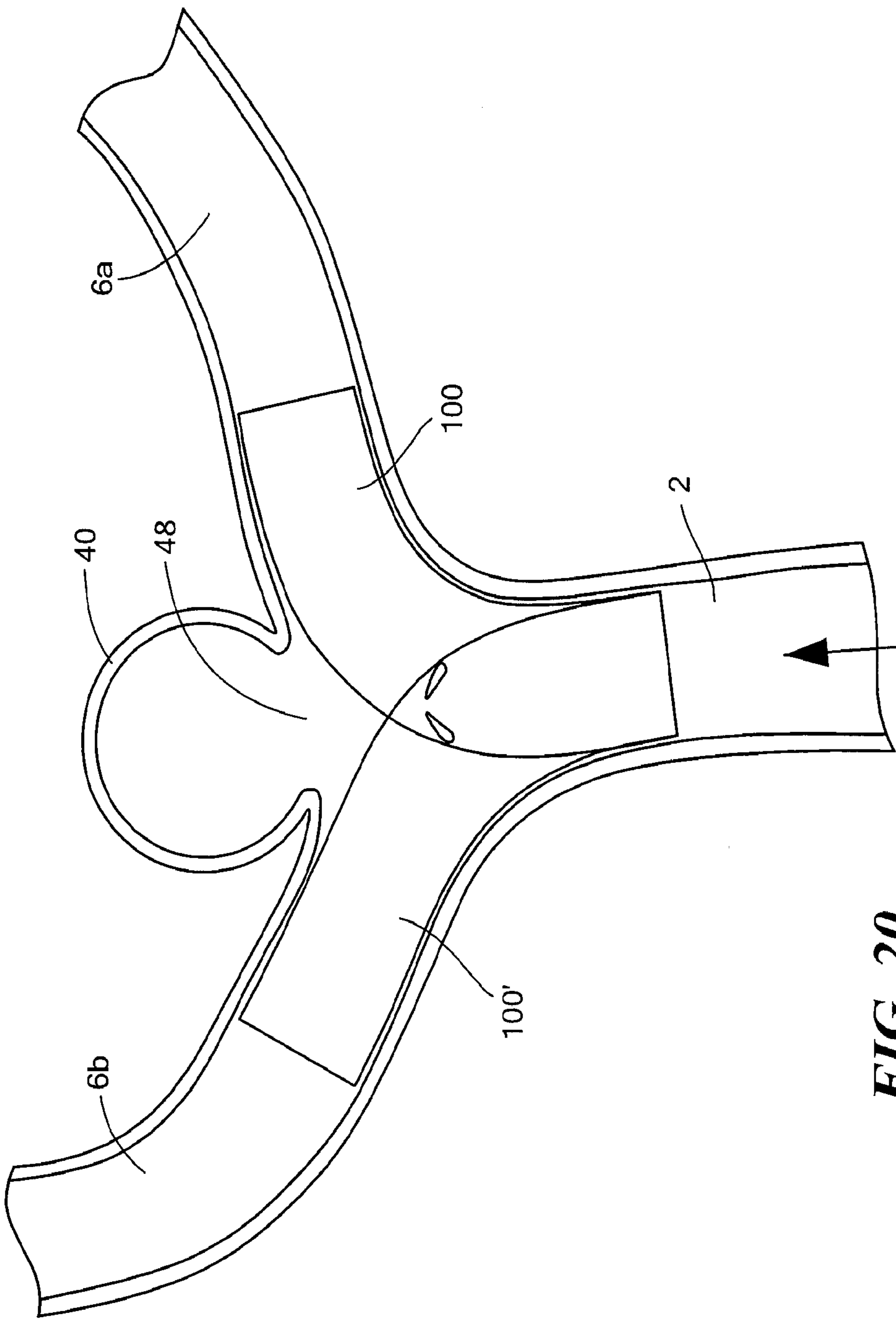



FIG. 20

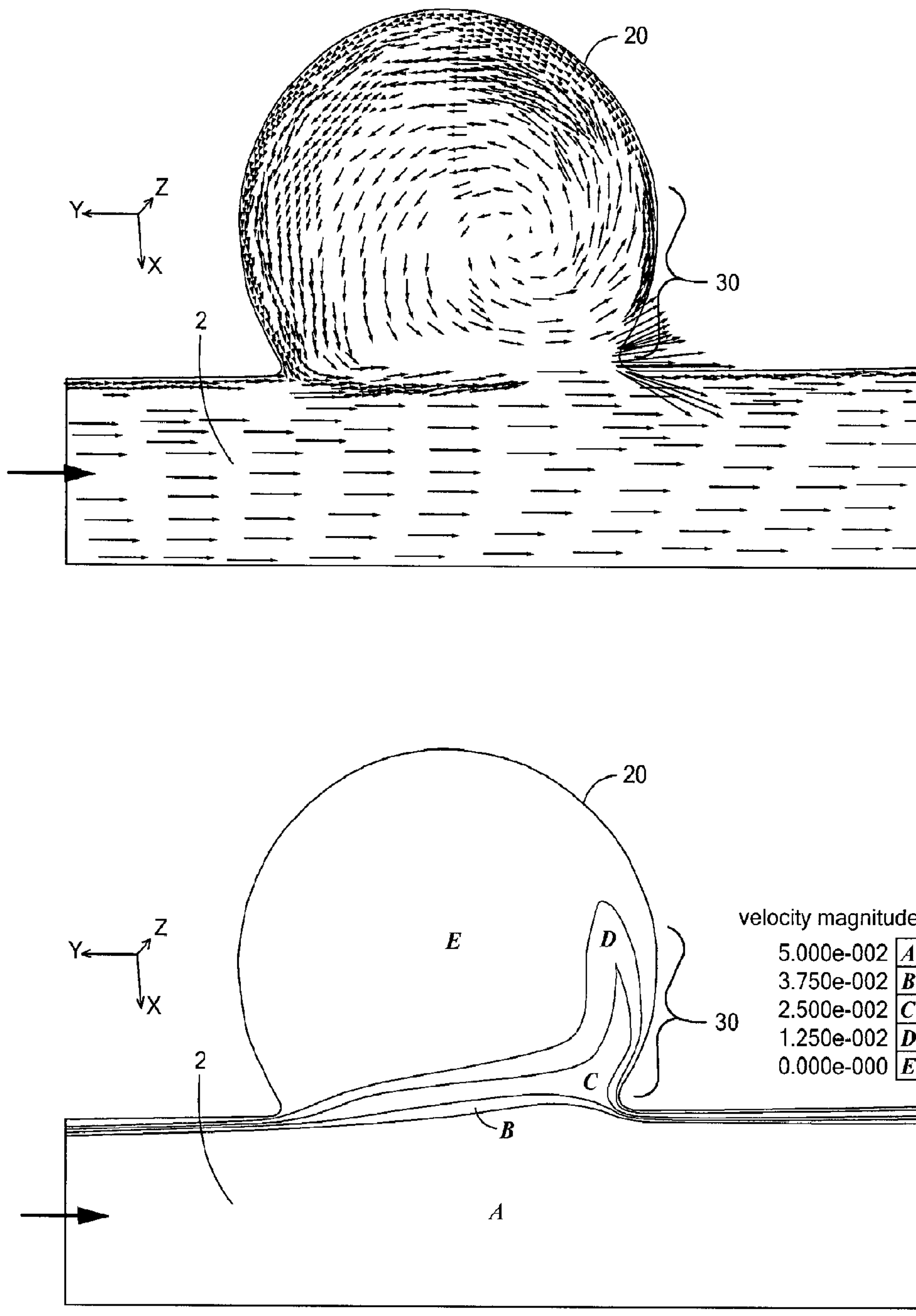

20
Z
Y
X
30
2
20
velocity magnitude
5.000e-002 A
3.750e-002 B
2.500e-002 C
1.250e-002 D
0.000e-000 E
E
D
C
B
A
Z
Y
X
30
2

*FIG. 21*

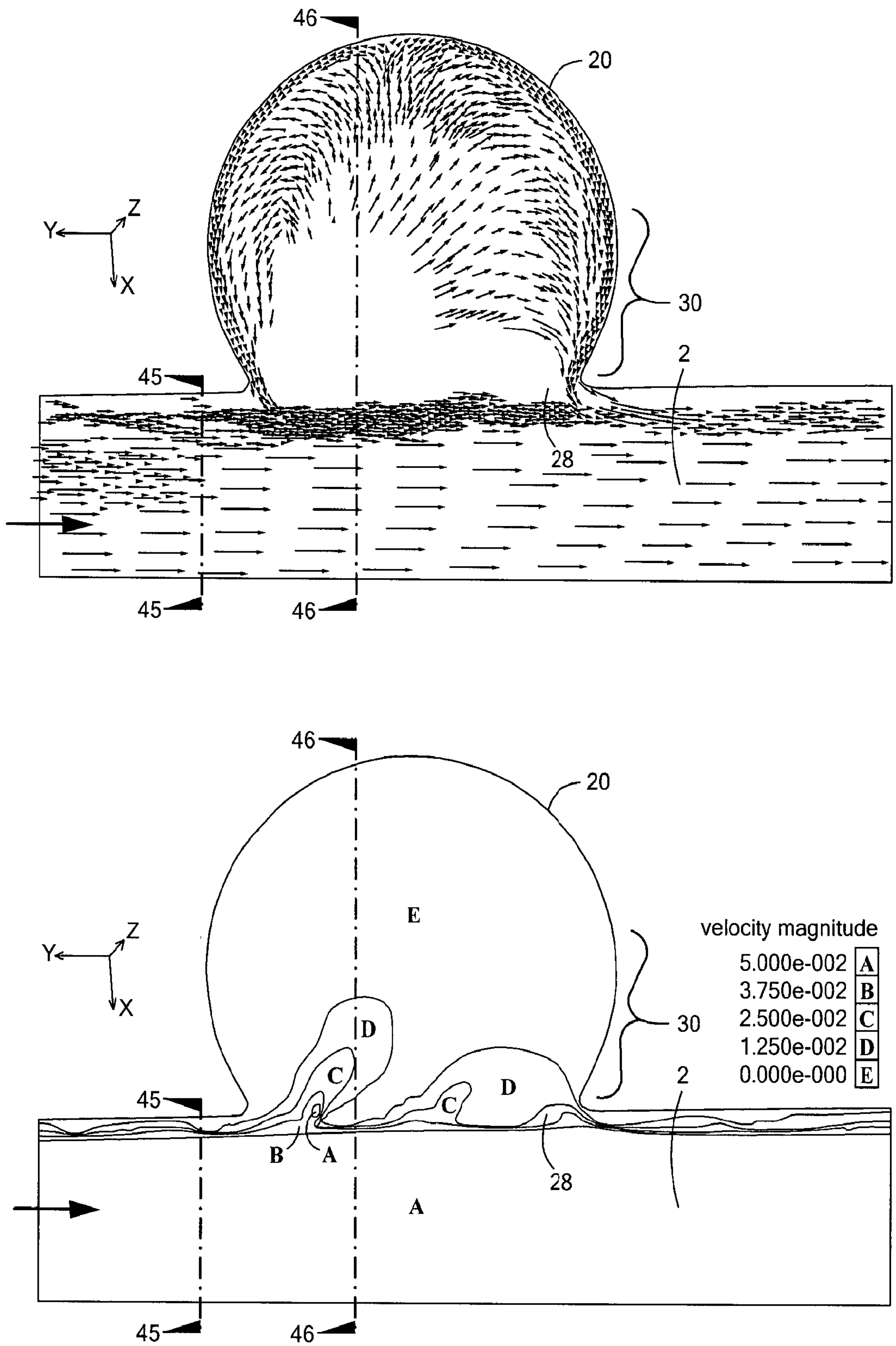
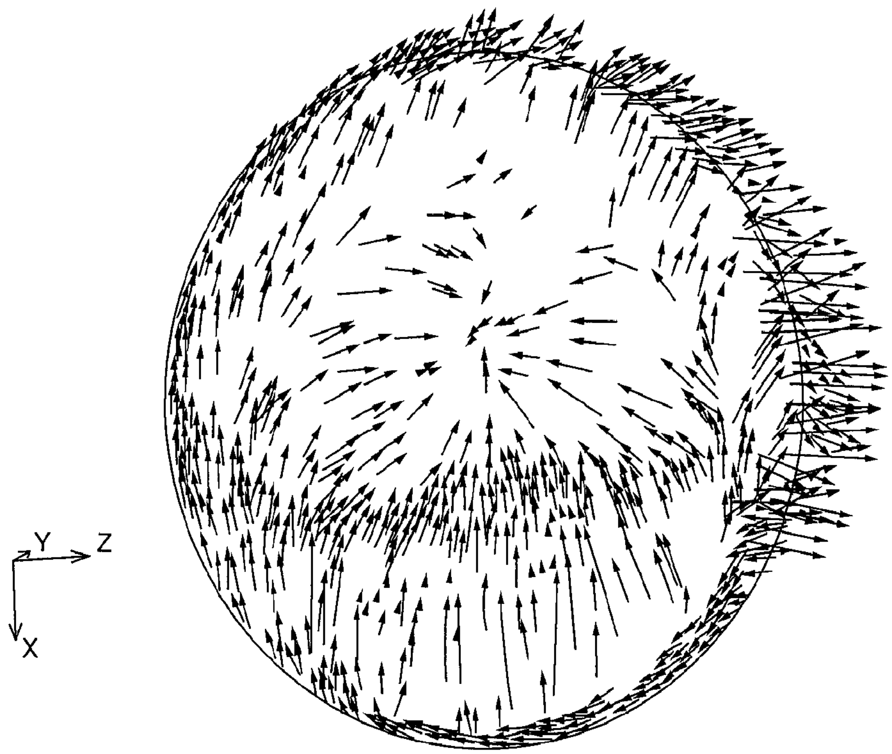
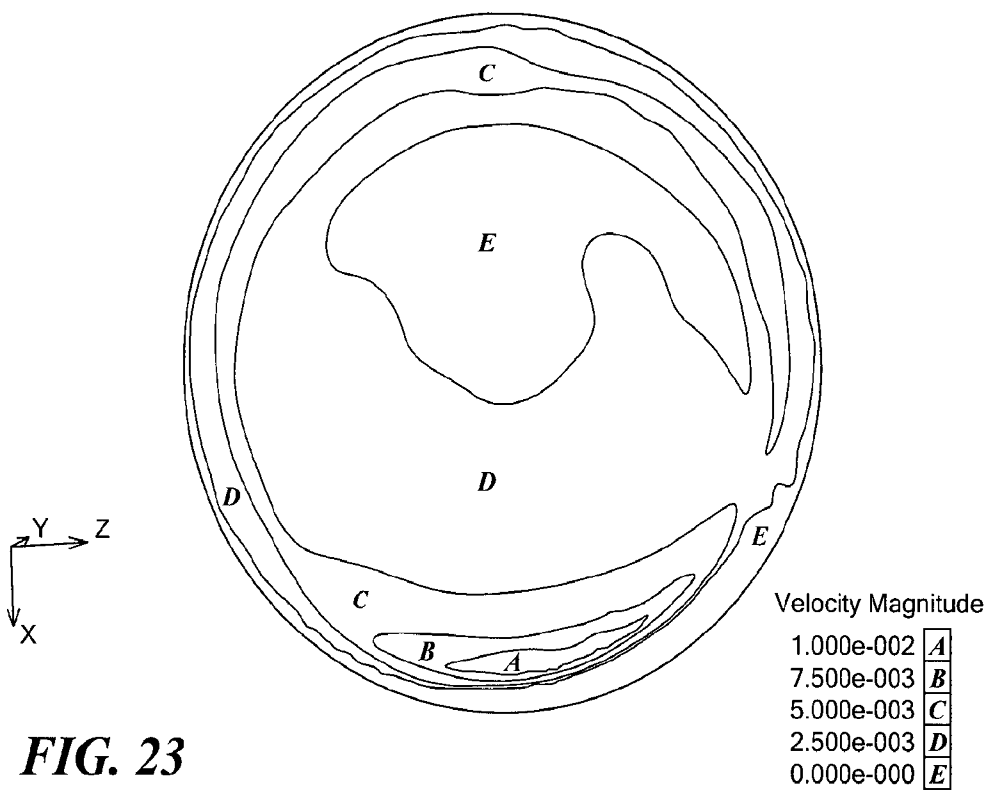

46
20
Y
Z
X
30
2
45
28
45
46
46
20
E
velocity magnitude
5.000e-002 A
3.750e-002 B
2.500e-002 C
1.250e-002 D
0.000e-000 E
Y
Z
X
D
30
C
2
45
C
D
B
A
28
A
45
46

*FIG. 22*


Y
Z
X


C
E
D
D
E
C
B
A
Y
Z
X
Velocity Magnitude
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7.500e-003 B
5.000e-003 C
2.500e-003 D
0.000e-000 E

*FIG. 23*

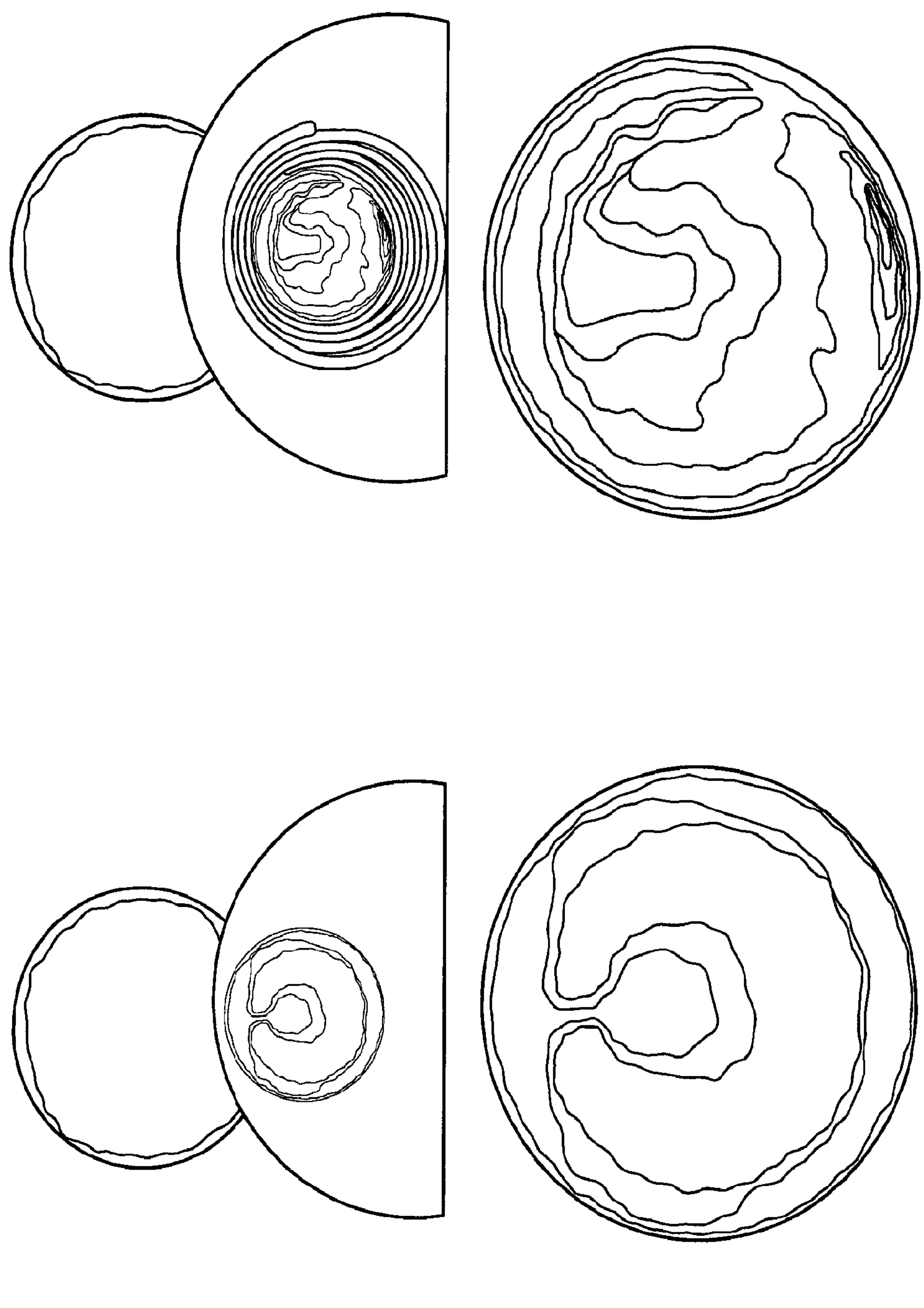

FIG. 24

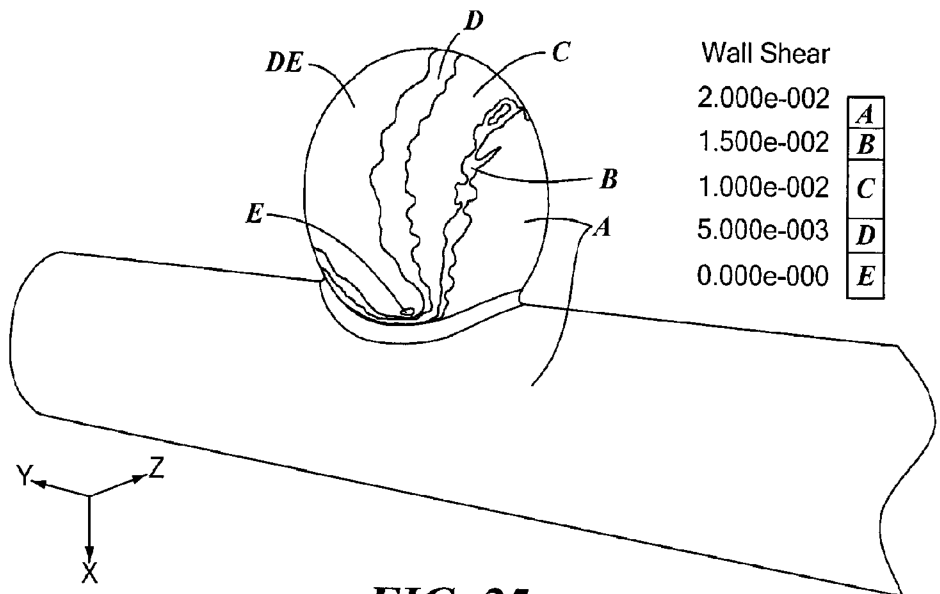
D
DE
C
Wall Shear
2.000e-002
A
1.500e-002
B
1.000e-002
C
5.000e-003
D
0.000e-000
E
B
E
A
Y
Z
X

FIG. 25

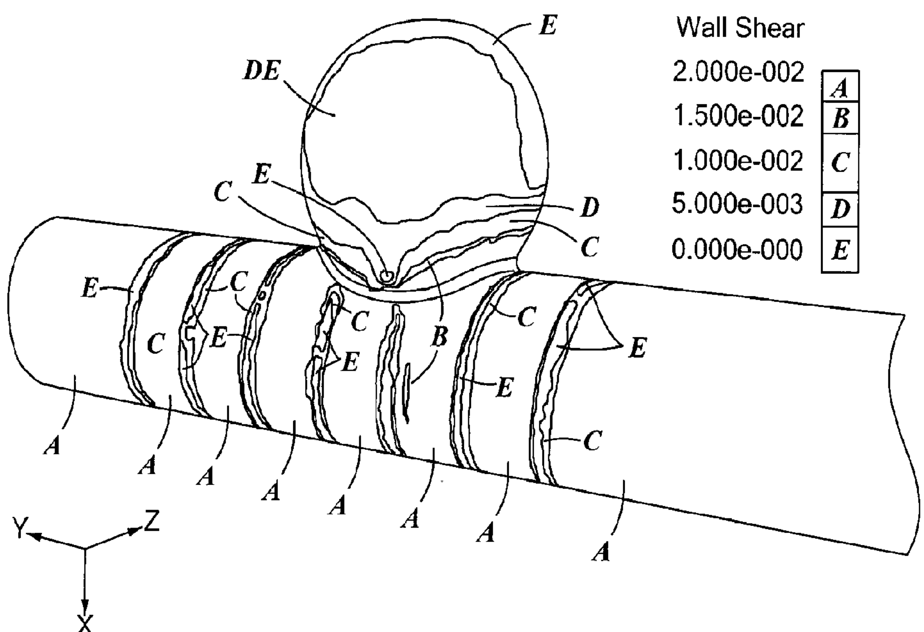
E
DE
Wall Shear
2.000e-002
A
1.500e-002
B
1.000e-002
C
5.000e-003
D
0.000e-000
E
C
E
D
C
E
C
C
E
C
E
B
C
E
E
C
A
A
A
A
A
A
A
A
Y
Z
X

FIG. 26

# ENDOVASCULAR STENT

## CROSS REFERENCE TO RELATED APPLICATIONS

This application is a National Stage of International Application No. PCT/US2012/021671 filed on Jan. 18, 2013, which claims priority to U.S. Provisional Application No. 61/435,592, filed Jan. 24, 2011, the contents of which are incorporated herein by reference in their entirety.

## BACKGROUND OF THE INVENTION

A brain aneurysm, also called an intracranial aneurysm, is an abnormal bulge or ballooning in a blood vessel supplying the brain. The weakened area forms a sac that fills with blood. Intracranial aneurysms can rupture and cause bleeding into the brain. Usually this occurs in the area between the brain and the surrounding membrane (the arachnoid), called the subarachnoid space, causing a subarachnoid hemorrhage. Subarachnoid hemorrhage resulting from a ruptured intracranial aneurysm occurs approximately 35,000 times per year in the United States.

Currently, intracranial aneurysms are treated by microsurgical clipping or endovascular coiling. In the latter, the goal is to prevent aneurysm rupture by inserting a thin wire into the aneurysm forming a coiled structure which blocks blood flow into the aneurysm. In some treatment paradigms, intracranial stents are used within the blood vessel to buttress placement of coils. Such stents serve as a mechanical scaffold in order to help contain the coil mass within the aneurysm dome.

## SUMMARY

In some aspects, an intravascular stent for treatment of an aneurysm in a vessel wall of a cranial blood vessel is provided. The aneurysm protrudes from, and defines an opening in, the vessel wall. The stent includes a flow-shaping member including a flow-facing surface that protrudes from an inner surface of the stent and is configured to control at least one of the direction, velocity and secondary flow characteristics of the blood flow within the aneurysm.

The stent may include one or more of the following features: The stent is configured to control blood flow both within the aneurysm and within the vessel in the vicinity of the aneurysm. The aneurysm has an inflow region adjacent a downstream side of the opening, where downstream is determined relative to a direction of blood flow within the vessel, and the stent is configured to control the blood flow within the aneurysm by directing blood flow away from the inflow region. The stent includes a series of axially spaced-apart annular struts in which adjacent struts are joined by axially extending links, and the flow-shaping surface is provided by a surface of at least one strut. The stent includes a single helically coiled strut, and the flow-shaping surface is provided by a surface of at least a portion of the strut. The stent includes a plurality of struts arranged to form a cylindrical body, and wherein the flow-shaping member comprises a vane protruding from an inner surface of the stent. The stent is configured to be disposed in the vessel so that the flow-shaping member extends at least partially across the opening while permitting substantially unobstructed blood flow into the aneurysm. The stent is configured to be disposed in the vessel so that the flow-shaping member is disposed in the vessel at a location upstream of the opening.

The stent may include one or more of the following additional features: The flow-shaping member protrudes inward from the inner surface of the stent so that the flow-facing surface extends in a non-normal direction relative to the inner surface of the stent. The flow-facing surface is disposed at an acute deflection angle that is measured relative to the inner surface of the stent. The deflection angle is in the range of 2 degrees to 60 degrees. The deflection angle is in the range of 3 degrees to 30 degrees. The deflection angle is in the range of 4 degrees to 15 degrees. The deflection angle of the flow-facing surface is configured to divert at least a portion of the blood flow toward an axial centerline of the stent. The deflection angle of the flow-facing surface is configured to divert at least a portion of the blood flow in a direction tangential to an axial centerline of the stent.

The stent may include one or more of the following additional features: The flow-shaping member has a generally elliptical cross section, the flow-shaping member being oriented so that the long axis of the elliptical cross section is angled relative to an inner surface of the stent. The flow-shaping member has a generally rectangular cross section, the flow-shaping member being oriented so that the long axis of the rectangular cross section is angled relative to an inner surface of the stent. The stent includes two vanes, the vanes being elongated and each including a first portion aligned with an axial direction of the vessel, and a second portion angled relative to the first portion. The second portion extends in a circumferential direction of the stent. The second portion extends in a radial direction of the stent. The two vanes are arranged so that a second portion of the first strut is disposed within the opening, and the second portion of the second strut overlies the first portion of the first strut. The two vanes are arranged so that the respective first portions are parallel to an axial direction of the strut, and the respective second portions are diverging.

The stent may include one or more of the following additional features: The flow-facing surface of each annular strut is disposed at an acute deflection angle that is measured relative to the inner surface of the stent. The deflection angle varies about a circumference of an annular strut. A first portion of one of the annular struts has a first deflection angle, a second portion of the one of the annular struts has a second deflection angle, and the first deflection angle is different from the second deflection angle. The first deflection angle is orthogonal to the second deflection angle. The first deflection angle is an acute angle, and the second deflection angle is zero. The first and second portions arc diametrically opposed.

The stent may include one or more of the following additional features: The flow-facing surface is configured to direct flow in a first direction, and the stent further comprises a second flow-shaping member including a second flow-facing surface configured to direct flow in a second direction that is different from the first direction. The flow-shaping members have the same shape. The flow-shaping members have different shapes. The first direction is orthogonal to the second direction. The first direction includes a flow-direction component in a first axial direction of the stent, and the second direction includes a flow-direction component in a direction opposed to the first axial direction of the stent. The stent includes a strut having a generally elliptical cross section, the long axis of the elliptical cross section being angled relative to a longitudinal axis of the stent so that the strut protrudes into the flow, the strut extending axially along a helical path, the helical path having a helix angle of greater than 60 degrees.

In some aspects, an intravascular stent is provided that is configured to modify vascular blood flow. The stent includes a vane including a flow-facing surface that protrudes from an inner surface of the stent and is configured to disrupt laminar blood flow within the stent.

The intracranial stent disclosed herein includes struts having a shape, orientation and thickness that advantageously impart changes to the blood flow characteristics within the aneurysm, within the stent, and/or within the blood vessel in the vicinity of the stent. By doing so, it is possible to shield the aneurysm from the various hemodyamic forces which can lead to its growth or rupture. Such changes may include one or more of blood flow velocity, direction and secondary blood flow characteristics including laminarity of blood flow. This is in contrast to some conventional stents in which stent struts are relied on as non-obstructive scaffolding within the vascular lumen.

Among other advantages, the intracranial stent locally alters one or more of the blood flow velocity, direction and/or secondary flow characteristics such as laminarity of flow. As a result blood flow and vessel wall shear forces are controlled within one or both of the aneurysm and the vessel in the vicinity of the aneurysm. Use of a stent to deliberately cause disruption of blood flow is clearly unconventional, since some blood flow disruptions, for example greater disruptions than those introduced by the disclosed stent, are associated with stenosis and thrombosis. To avoid these effects, some conventional stents such as intracoronary stents are designed to minimize disturbance of blood flow within the vessel, and to promote laminar blood flow.

Modes for carrying out the present invention are explained below by reference to an embodiment of the present invention shown in the attached drawings. The above-mentioned object, other objects, characteristics and advantages of the present invention will become apparent from the detailed description of the embodiment of the invention presented below in conjunction with the attached drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic side sectional view of a stent disposed within a blood vessel having a side wall aneurysm, the stent including a flow-shaping member.

FIG. **2***a* is a perspective view of a stent formed of a helically wound strut disposed within a blood vessel having a side wall aneurysm.

FIG. **2***b* is an enlarged view of a portion of the stent of FIG. **2**.

FIG. **3***a* is schematic side sectional view of an alternative embodiment stent formed of an annular strut disposed within a blood vessel having a side wall aneurysm.

FIG. **3***b* is a schematic top sectional view of the stent of FIG. **3***a*.

FIG. **4***a* is schematic side sectional view of another alternative embodiment stent formed of an annular strut disposed within a blood vessel having a side wall aneurysm.

FIG. **4***b* is a schematic top sectional view of the stent of FIG. **4***a*.

FIG. **5***a* is schematic side sectional view of another alternative embodiment stent formed of an annular strut disposed within a blood vessel having a side wall aneurysm.

FIG. **5***b* is a schematic top sectional view of the stent of FIG. **5***a*.

FIG. **6***a* is schematic side sectional view of another alternative embodiment stent formed of an annular strut disposed within a blood vessel having a side wall aneurysm.

FIG. **6***b* is a schematic top sectional view of the stent of FIG. **6***a*.

FIG. **7***a* is a side sectional view of a stent disposed within a blood vessel having a side wall aneurysm, the stent including an open cell strut structure and a vane protruding from an inner surface of the stent.

FIG. **7***b* is schematic side sectional view of the stent of FIG. **7***a*.

FIG. **7***c* is a schematic top sectional view of the stent of FIG. **7***b*.

FIG. **8***a* is schematic side sectional view of an alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **8***b* is a schematic top sectional view of the stent of FIG. **8***a*.

FIG. **9***a*-**9***f* are transverse sectional views of the stent of FIG. **7***c* as seen along line **2**-**2** illustrating possible variations in vane profile.

FIG. **10***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **10***b* is a schematic top sectional view of the stent of FIG. **10***a*.

FIG. **11***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **11***b* is a schematic top sectional view of the stent of FIG. **11***a*.

FIG. **12***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **12***b* is a schematic top sectional view of the stent of FIG. **12***a*.

FIG. **13***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **13***b* is a schematic top sectional view of the stent of FIG. **13***a*.

FIG. **14***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **14***b* is a schematic top sectional view of the stent of FIG. **14***a*.

FIG. **15***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **15***b* is a schematic top sectional view of the stent of FIG. **15***a*.

FIG. **16***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **16***b* is a schematic top sectional view of the stent of FIG. **16***a*.

FIG. **17***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **17***b* is a schematic top sectional view of the stent of FIG. **17***a*.

FIG. **18***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **18***b* is a schematic top sectional view of the stent of FIG. **18***a*.

FIG. **19***a* is schematic side sectional view of another alternative embodiment stent disposed within a blood vessel having a side wall aneurysm.

FIG. **19***b* is a schematic top sectional view of the stent of FIG. **19***a*.

FIG. **20** is a schematic side sectional view of a pair of stents disposed within a blood vessel having a bifurcation aneurysm, each stent including a flow-shaping member.

FIG. **21** is a side sectional view of a blood vessel including a sidewall aneurysm without a stent illustrating calculated blood flow direction (fine arrows) and velocity (labeled regions).

FIG. **22** is a side sectional view of the blood vessel of FIG. **21** including a sidewall aneurysm treated with the stent of FIG. **2***a*, illustrating calculated blood flow direction (fine arrows) and velocity (labeled regions).

FIG. **23** is a transverse sectional view of the blood vessel of FIG. **22** as seen along line **45-45** illustrating calculated blood flow direction (fine arrows) and velocity (labeled regions).

FIG. **24** are transverse sectional views of the blood vessel of FIG. **22** as seen along line **46-46** illustrating calculated blood flow direction (fine arrows) and velocity (labeled regions).

FIG. **25** is a perspective view of the blood vessel of FIG. **21** illustrating calculated wall shear stress for an untreated aneurysm.

FIG. **26** is a perspective view of the blood vessel of FIG. **22** illustrating calculated wall shear stress for an aneurysm treated with the stent of FIG. **2***a*.

## DETAILED DESCRIPTION

Referring to FIG. **1**, a stent **100** is disposed within a blood vessel **2** that includes a sidewall aneurysm **20**. As used herein, the term “sidewall aneurysm” refers to a type of aneurysm in which the blood vessel **2** forms an outward bulge from one portion of the vessel sidewall **4**, defining an aneurysm opening **28** in the vessel sidewall **4**. The stent **100** is placed within the blood vessel lumen **8** so as extend across the aneurysm opening **28**.

In general and as will be discussed, the stent **100** includes internal blood flow-shaping members **102** (represented schematically in FIG. **1**) that modify and direct blood flow within the blood vessel **2** in the vicinity of the stent **100**, within the stent **100**, and/or within the aneurysm **20**, as discussed further below. By doing so, the hemodynamics and vessel wall shear forces are controlled to induce desired characteristics that can useful for aneurysm treatment. For example, in some embodiments, the stent **100** includes flow-shaping members **102** that may control the blood flow in such a way as to favor progression of thrombosis within the aneurysm **20**. In other embodiments, the stent **100** may include flow-shaping members **102** that may control the blood flow to generate a different effect, such as altering blood flow velocity and or direction within the aneurysm **20**, whereby vessel wall shear forces within the aneurysm **20** are reduced. In yet other embodiments, the stent **100** may include flow-shaping members **102** that may control the blood flow to generate a still different effect, such as altering blood flow velocity and or direction in a portion of the blood vessel **2** upstream from the aneurysm **20** relative to the blood flow direction whereby shear forces within the aneurysm **20** are reduced. In the figures, the blood flow direction within the vessel **2** is indicated by an arrow. Throughout the following description, the terms “upstream” and “downstream” are made with reference to the direction of blood flow within the vessel **2**.

Referring also to FIGS. **2***a* and **2***b*, stent **100** is a hollow cylindrical member having a stent outer surface **144** and a stent inner surface **146**. The stent **100** may be self-expanding and may be implanted via a delivery catheter (not shown). The stent **100** is formed of a single coiled wire strut **148** formed of a metal filament that is wound into a helical shape, and which serves as a flow-shaping member, as discussed further below. In some embodiments, the strut **148** has a thickness in the range of 45 to 60 μm, and as such is thin relative to struts used to form non-intracranial stents, including for example cardiac stents. The relative thinness of the stent **100** is required to accommodate the relative delicacy of the intracranial blood vessels **2** in which they are deployed. For example, although when deployed stent **100** expands to correspond to the size of the vessel lumen **8**, the stent **100** does not embed within the vessel walls **4** reflecting the relative thinness and fragility of the vessel walls. The stent **100** is polished to prevent unwanted areas of thrombosis and restenosis and may also be coated with a bio-degradable lubricious coating to facilitate deployment and decrease friction during use.

The coiled wire strut **148** of the stent **100** is formed having a large number of coil turns for a given stent length, whereby the helix angle $\alpha$, or angle of the strut **148** relative to an axial direction **16** of the blood vessel **2**, is relatively large. For example, the helix angle $\alpha$ is desired to be at least 55 degrees. In the illustrated embodiment the helix angle $\alpha$ is about 83 degrees.

In addition the coiled wire strut **148** is provided with an elongated cross-section that includes a flow-facing surface **160** and a vessel facing surface **162** that is opposed to the flow-facing surface **160**. The flow-facing and vessel facing surfaces **160**, **162** are relatively long compared to the thickness of the strut **148** and are generally parallel to a long axis **164** of the strut cross section. In the illustrated embodiment, the cross sectional shape of the strut **148** is generally elliptical, such that it acts as a hydrofoil.

In order to direct blood flow away from the vessel wall **4**, the strut **148** is arranged so that the cross-sectional long axis **164** of the strut **148** is oriented at a deflection angle $\theta$ relative to the inner surface **8** of the blood vessel **2**. As a result, the strut **148** protrudes inward from vessel wall **4** so that the flow-facing surface **160** extends in a non-normal direction relative to vessel wall **4**. In some embodiments, the deflection angle $\theta$ is in the range of 2 degrees to 60 degrees. In other embodiments, the deflection angle $\theta$ is in the range of 3 degrees to 30 degrees. In the illustrated embodiment, the deflection angle $\theta$ is about 25 degrees. Due to the angled configuration of the flow-facing surface **160** of the strut **148**, blood flow direction is diverted so as to include at least a component directed in the radial direction of the stent **100**, that is, toward an axial centerline of the stent **100**. In addition, due to the helical configuration of the strut **148**, blood flow direction is diverted so as to include another component directed in a circumferential (tangential) direction of the stent **100**, that is, a rotational component about an axial centerline of the stent **100**.

It should be noted that although the stent **100** is positioned in the vicinity of the aneurysm **20** so that portions of several turns of the coiled wire strut **148** extend across the aneurysm opening **28**, sufficient spacing S is provided between adjacent turns of the strut **148** so that the stent **100** does not act as a barrier preventing flow into the aneurysm **20**. Rather, the strut **148** deflects a portion of the blood flow away from the aneurysm opening **28**, while permitting blood flow through the aneurysm opening **28** in a directed manner.

Although the cross sectional shape of the strut **148** of the stent **100** is disclosed as being generally elliptical, the strut is not limited to this shape. For example, the strut **148** may have other cross sectional shapes, including, but not limited to circular, rectangular, or tear-drop.

Although in the illustrated embodiment, the deflection angle $\theta$ of the strut **148** of the stent **100** is uniform along the length of the strut **100**, the deflection angle $\theta$ is not limited to being uniform. For example, the deflection angle $\theta$ can be non-uniform such that portions of the strut in adjacent turns can have different deflection angles $\theta$. Similarly, although in the illustrated embodiment, the helix angle α of the strut **148** of the stent **100** is uniform along the length of the strut **100**, the helix angle a can vary along the length of the strut **100**.

Referring to FIGS. **3-10**, an alternative stent **200** also includes internal blood flow-shaping members that modify and direct blood flow within the blood vessel **2** in the vicinity of the stent **200**, within the stent **200**, and/or within the aneurysm **20**. The stent **200** is a hollow cylindrical member formed of annular struts **248** arranged in series along an axial direction of the strut **200**, in which adjacent struts **248** are mutually spaced apart and connected using axially extending links **250**. Each annular strut **248** is formed of a metal filament that is arranged into a generally circular shape. Like the wire strut **148** of the previous embodiment, the strut **248** has a thickness in the range of 45 to 60 μm. The stent **200** is polished to prevent unwanted areas of thrombosis and restenosis and may also be coated with a bio-degradable lubricious coating to facilitate deployment and decrease friction during use.

At least one annular strut **248** serves as a flow-shaping member. Each annular strut **248** is provided with an elongated cross-section and includes a flow-facing surface **260** and a vessel facing surface **262** that is opposed to the flow-facing surface **260**. The flow-facing and vessel facing surfaces **260**, **262** are relatively long compared to the thickness of the strut **248**, and are generally parallel to a long axis **264** of the strut cross section. In the illustrated embodiment, the cross sectional shape of the strut **248** is generally elliptical, such that it acts as a hydrofoil.

The stent **200** is positioned in the vicinity of the aneurysm **20** so that portions of two or more annular struts **248** extend across the aneurysm opening **28**. Like the previous embodiment, sufficient spacing S is provided between adjacent annular struts **248** so that the stent **200** does not act as a barrier preventing flow into the aneurysm **20**. Rather, the individual struts **248** each deflect a portion of the blood flow away from the aneurysm opening **28**, while permitting blood flow through the aneurysm opening **28** in a directed manner.

In order to direct a portion of the blood flow away from the vessel wall **4**, the long axis **264** of the strut **248** is oriented at a deflection angle θ relative to the inner surface **8** of the blood vessel **2**.

Referring particularly to FIGS. **3***a* and **3***b*, the stent **200** includes annular struts **248** that are each formed to have a uniform deflection angle θ1 about the circumference of the vessel **2**, such that each strut **248** has the same deflection angle θ1 along a first side **34** of the vessel **2** corresponding to the aneurysm **20** and along a second side **36** of the vessel that is opposed to the first side **34**.

Referring to FIGS. **4***a* and **4***b*, a variation in annular strut configuration is illustrated with respect to a stent **200***a* that includes an annular strut **248***a* that is formed to have a first deflection angle θ1 along the first side **34** of the vessel **2**, and a second deflection angle θ2 along the second side **36** of the vessel **2**. For example, the first and second deflection angles θ1, θ2 may be generally equal in magnitude and have opposed directions.

Referring to FIGS. **5***a* and **5***b*, another variation in annular strut configuration is illustrated with respect to a stent **200***b* that includes annular struts **248***b* that are formed to have a first deflection angle θ1 along the first side **34** of the vessel **2**, and a second deflection angle θ2 along the second side **36** of the vessel. For example, in the illustrated embodiment, the first angle θ1 is acute, and the second angle θ2 is substantially zero. A shown in FIG. **5***b*, the deflection angle of the annular strut **248***b* smoothly transitions between T1 and T2, such that the deflection angle θ3 along a side of the vessel **2** between the first side **34** and second sides **36** is θ1<θ3<θ2.

Referring to FIGS. **6***a* and **6***b*, still another variation in annular strut configuration is illustrated with respect to a stent **200***c* that includes annular struts **248***c*. Like the stent **200** shown in FIGS. **3** and **4**, the stent **200***c* includes annular struts **248***c* that are formed to have a uniform angle θ1 about the circumference of the vessel **2**. However, adjacent annular struts **248***c***1**, **248***c***2** . . . are provided with different deflection angles. For example, in the illustrated embodiment, one strut **248***c***1** has first deflection angle θ1, and the adjacent strut **248***c***2** has a second deflection angle θ2. The second deflection angle θ2 may differ in magnitude and or direction from the first deflection angle θ1. In some embodiments, the first and second deflection angles θ1, θ2 may be mutually orthogonal.

In each of the stents **200**, **200***a*, **200***b*, **200***c*, the annular strut **248** protrudes inward from vessel wall **4** so that the flow-facing surface **260** extends in a non-normal direction relative to vessel wall **4**. In some embodiments, the deflection angle θ is in the range of 2 degrees to 60 degrees. In other embodiments, the deflection angle θ is in the range of 3 degrees to 30 degrees. In still other embodiments, the deflection angle θ is in the range of 4 degrees to 15 degrees. Due to the angled configuration of the flow-facing surface **260** of the strut **148**, blood flow direction is diverted so as to include at least a component directed in the radial direction of the stent **200**, that is, toward an axial centerline of the stent **200**. In addition, due to the annular configuration of the strut **248**, blood flow direction may also diverted so as to include another component directed in a circumferential (tangential) direction of the stent **200**, that is, a rotational component about an axial centerline of the stent **200**.

Referring to FIG. **7***a*-**7***c*, another alternative stent **300** includes internal blood flow-shaping members (shown schematically in FIG. **11** as **302**) that modify and direct blood flow within the blood vessel **2** in the vicinity of the stent **300**, within the stent **300**, and/or within the aneurysm **20**. The stent **300** is a hollow cylindrical member formed of thin metal filament struts **348** arranged in an open cell structure. Unlike previous embodiments in which the struts **148**, **248** provided the flow-shaping member, the struts **348** of the stent **300** are minimally disruptive to blood flow, and instead merely provide a scaffold within the blood vessel **2** and a support structure to which at least one flow-shaping member **302** is mounted. The stent **300** has an open first end **340** corresponding to the flow inlet end, and a second end **342** opposed to the first end and corresponding to the flow outlet end. The stent **300** has an outer surface **344** and an inner surface **346**, is polished to prevent unwanted areas of thrombosis and restenosis, and may also be coated with a bio-degradable lubricious coating to facilitate deployment and decrease friction during use.

Each flow-shaping member **302** includes a flow-facing surface **360**, and a leeward surface **362** that is opposed to the flow-facing surface **360**.

Referring to FIGS. **7***a* and **7***b*, the stent **300** includes a flow-shaping member **302** in the form of a vane **302***a* disposed generally midway between the stent first and second ends **340**, **342**. The vane **302***a* protrudes inward from an inner surface **346** of the stent **300**. The vane **302***a* extends along a portion of the circumference of the stent **300**. In the illustrated embodiment, the vane **302***a* is elongated in the circumferential direction such that it has a width w**1** that is greater than the width wo of the aneurysm opening **28**. The vane **302***a* protrudes inward from the stent inner surface **346** so that the flow-facing surface **360** extends in a non-normal direction, and defines a deflection angle θ relative to the stent inner surface **346**. In the embodiment shown in FIGS. **12** and **13**, the stent **300** is disposed in a blood vessel **2** so that the vane

**302a** is positioned at a location corresponding to the first side **34** of the vessel **2**, and so that the vane **302a** is disposed at a location corresponding to the aneurysm opening **28**.

As seen in FIGS. **8a** and **8b**, a variation in vane position is illustrated with respect to a stent **300b** that includes a vane **302b** that is identical to the vane **302a** except that it is not positioned at a location corresponding to the aneurysm opening **28**. For example, the vane **302b** is positioned upstream of the aneurysm opening **28**.

Referring to FIGS. **9a**-**9f**, when viewed in the axial direction of the stent **300** the vanes **302a**, **302b** may have any appropriate profile required to achieve the desired blood flow characteristics. For example, the vane profile may be rectangular (FIG. **9a**), or may be arcuate (FIGS. **9b**-**9f**) so as to conform to the inner periphery of the stent **300**. In addition, the vane ends may be formed to protrude stepwise from the stent inner surface **346** (FIGS. **9a** and **9b**) or may taper smoothly from the stent inner surface **346** (FIGS. **9c**-**9f**). In some embodiments, the vane profile may be irregular so as to include one or more protrusions **330**, **331** (FIGS. **9d**-**9e**). In some embodiments the vane **302** may include perforations **332** (FIG. **9f**).

As seen in FIGS. **10a** and **10b**, a variation in vane size is illustrated with respect to a stent **300c** that includes a vane **302c** that is identical to the vane **302b** except that it is of a relatively short dimension in the in the circumferential direction. For example, the vane **302c** is has a width w**2** that is at most one half the width wo of the aneurysm opening **28**.

Referring to FIGS. **11a**-**14b**, examples of possible variations in vane shape are illustrated. The vane **302** may have any shape that is appropriate to achieve the desired blood flow characteristics. The following examples are non-limiting, and are presented to illustrate some of the possible vane shape variations that may be used to modify and direct blood flow within the blood vessel **2** in the vicinity of the stent **200**, within the stent **200**, and/or within the aneurysm **20**.

Referring now to FIGS. **11a** and **11b**, a variation in vane shape is illustrated with respect to a stent **300d** that includes a vane **302d** that is an elongated, thin body that is arranged along the stent inner surface **346** so that an axial direction of the vane is aligned with the axial direction of the stent **300d**. The vane includes a first end **304**, a second end **306** disposed downstream relative to the first end **304**, and a mid portion **308** disposed between the first and second ends **304**, **306**. The vane **302d** is curved to form a generally ski-shape such that the first end **304** and mid portion **308** are contiguous with the stent inner surface **346**, and such that the second end **306** curves away from the stent inner surface **346**. In the illustrated embodiment, the second end **306** curves radially inward toward the axial centerline of the stent **300d**. In some embodiments, the second end **306** is positioned at a location corresponding to the aneurysm opening **28**, but the vane **300d** is not limited to this position. In some embodiments, the stent **300d** includes more than one vane **302d**. For example, two vanes **302d** may be provided that are arranged generally end-to-end along the axial direction of the stent **300d** such that they are slightly overlapping along the axial direction of the stent **300d**. In this embodiment, the blood flow within the stent **300d** is redirected in a radially inward direction due to the shape and orientation of the second end **306** of the vane **302d**.

Referring to FIGS. **12a** and **12b**, another variation in vane shape is illustrated with respect to a stent **300e** that includes a pair of vanes **302e** that are identical to the vanes **302d** of the preceding example, except that the vanes **302e** are arranged side by side so as to be spaced apart along a circumferential direction of the stent **300e**. In addition, the vanes **302e** are oriented so that each of the first end **304**, second end **306** and mid portion **308** are contiguous with the stent inner surface **346** such that the curved second end **306** extends along a circumferential direction of the stent **300e**. In this embodiment, the curved second ends **306** are positioned closely adjacent to the aneurysm opening **28** on an upstream side of the aneurysm opening **28**, and the blood flow within the stent **300e** is redirected in a circumferential (tangential) direction due to the shape and orientation of the second end **306** of the vane **302e**.

Referring to FIGS. **13a** and **13b**, another variation in vane shape is illustrated with respect to a stent **300f** that includes a vane **302f** that is generally V shaped. The vane **302f** is oriented so that an apex **310** of the vane **302f** is upstream relative to the diverging legs **312** of the vane **302f**. In addition, the vane **302f** may be positioned so that the diverging legs **302f** surround a portion of the aneurysm opening **28** along an upstream side thereof. In this embodiment, the blood flow within the stent **300f** is redirected in a circumferential (tangential) direction due to the diverging shape and orientation of the vane **302f**.

Referring to FIGS. **14a** and **14b**, another variation in vane shape is illustrated with respect to a stent **300g** that includes a vane **302g** that is generally rod shaped. The vane **302g** is oriented so that it protrudes generally radially inward from the stent inner surface **346** at a location adjacent to the aneurysm opening **28** on an upstream side thereof.

Referring to FIGS. **15a**-**19b**, examples of possible variations in vane configuration are illustrated. For illustration purposes, the examples are presented with reference to the rod-shaped vane **302g**, but one of ordinary skill will understand that vane configuration variations are not limited to the rod-shaped vane **302g**. Rather, the flow-shaping member **302** may be placed in any configuration that is appropriate to achieve the desired blood flow characteristics. The following examples are non-limiting, and are presented to illustrate some of the possible vane variations that may be used to modify and direct blood flow within the blood vessel **2** in the vicinity of the stent **200**, within the stent **200**, and/or within the aneurysm **20**.

Referring to FIGS. **15a** and **15b**, a variation in vane configuration is illustrated with respect to a stent **300h** that includes multiple rod-shaped vanes **302g**. In this example, three vanes **302g** are arranged in a spaced-apart relationship along a circumferential direction of the stent **300h**.

Referring to FIGS. **16a** and **16b**, another variation in vane configuration is illustrated with respect to a stent **300i** that includes two vanes **302g** that are positioned upstream of the aneurysm opening **28** and are arranged in a spaced apart relationship along an axial direction of the stent **300i**.

Referring to FIGS. **17a** and **17b**, another variation in vane configuration is illustrated with respect to a stent **300j** that includes two vanes **302g1**, **302g2**. Like the preceding embodiment, the vanes **302g1**, **302g2** are positioned upstream of the aneurysm opening **28** and are arranged in a spaced apart relationship along an axial direction of the stent **300i**. However, in the stent **300j**, the vanes **302g1**, **302g2** are provided having the same shape but differing in size. For example, a first vane **302g1** is shorter than a second vane **302g2**, and is positioned upstream relative to the second vane **302g2**.

Referring to FIGS. **18a** and **18b**, another variation in vane configuration is illustrated with respect to a stent **300k** that includes three vanes **302g3**, **302g4**, **302g4** are arranged within a stent **300k** in a spaced apart relationship so as to form a V configuration. In this example, the vane **302g3** that is located relatively upstream and corresponds to the apex of the V is shorter than the vanes **302g4** that correspond to the legs of the V.

Referring to FIGS. **19***a* and **19***b*, another variation in vane configuration is illustrated with respect to a stent **300***m* that includes two vanes **302***g*, **302***g*. This embodiment illustrates that the position of the vanes **302***g* is not limited to a side of the stent **300***m* corresponding to the aneurysm **20**. For example, two axially spaced vanes **302***g*, **302***g* having the same shape are provided on opposed sides of the stent **300***m*.

Although stent **300** is described here as having struts **348** that are arranged in an open cell structure, the stent **300** is not limited to this configuration. For example, in some embodiments the struts **348** may be arranged in a closed cell structure.

Referring to FIG. **20**, intracranial aneurysms are generally categorized into three types: a fusiform aneurysm in which the blood vessel wall forms a sausage like outward bulge about its entire circumference (not shown); a sidewall aneurysm **20** in which the blood vessel **2** forms an outward bulge from one portion of the sidewall **4** (FIG. **1**); and a bifurcated aneurysm **40** in which the blood vessel **2** forms a bulge at an intersection of blood vessel branches **6** (FIG. **20**). Although described herein with reference to treatment of a sidewall aneurysm **20**, the stents **100**, **200**, **300** described here are not limited to use with a sidewall aneurysm **20**, and can also be used with respect to a bifurcated aneurysm **40**. For example, when treating a bifurcation aneurysm **40**, two stents **100**, **100'** may be placed within the main vessel so that an end of one stent **100** extends into one vessel branch **6***a*, and an end of another stent **100'** extends into the other vessel branch **6***b*. In this case, both of the stents **100**, **100'** extend across the aneurysm opening **48** and include flow-shaping members. The stents **100**, **100'** may be identical, respective mirror images, or unique.

## EXAMPLE

The hemodynamic effects of placing a stent **100** including a helical coil wire flow disrupting strut **148** within a blood vessel **2** in the vicinity of an idealized side wall aneurysm **20** as shown in FIG. **2***a* have been analyzed using computational fluid dynamic techniques. Results of the analysis show that placement of a helical coil stent **100** as described results in a significant alteration of the flow within the aneurysm dome, and also leads to alterations in the downstream portion of the blood vessel **2**, as discussed further below.

Referring to FIG. **21**, fine arrows are used to indicate blood flow velocities and directions calculated for an unstented blood vessel **2** including the aneurysm **20**. This figure illustrates vortex type swirling within the aneurysm **20** that is typical of an untreated aneurysm. Of particular note is the high velocities present at an inflow region **30** of the aneurysm **20** located adjacent the downstream side of the aneurysm opening **28**, which are thought to contribute to aneurysm growth.

Referring to FIG. **22**, when the blood vessel **2** including the aneurysm **20** is treated with a stent **100**, the calculated blood flow velocities and directions are shown to be altered relative to the untreated vessel **2** shown in FIG. **43**. In particular, the region of relatively high velocity is diverted away from the inflow region **30**.

Referring to FIG. **23**, blood flow velocities and directions calculated for a cross section of the blood vessel upstream of the aneurysm are indicated by fine arrows. This figure illustrates that the helical stent **100** produces velocity components within the stent **100** that are directed both radially inward and circumferentially.

Referring to FIG. **24**, blood flow velocities and directions calculated for a cross section of the blood vessel **2** corresponding to the aneurysm opening **28**. This figure illustrates that the helical stent **100** produces velocity components within the stent **100** that are directed both circumferentially and radially inward away from the aneurysm.

Referring to FIGS. **25** and **26**, wall shear stresses calculated for the portion of the vessel including the aneurysm **20** are shown for a blood vessel **2** without a stent (FIG. **47**) and a blood vessel **2** including a stent **100** (FIG. **48**). Aneurysm inflow region wall shear stresses are clearly decreased for a blood vessel including the stent **100** relative to the untreated vessel **2**.

A selected illustrative embodiment of the invention is described above in some detail. It should be understood that only structures considered necessary for clarifying the present invention have been described herein. Other conventional structures, and those of ancillary and auxiliary components of the system, are assumed to be known and understood by those skilled in the art. Moreover, while a working example of the present invention has been described above, the present invention is not limited to the working example described above, but various design alterations may be carried out without departing from the present invention as set forth in the claims.

What is claimed is:

**1**. An intravascular stent for treatment of an aneurysm in a vessel wall of a cranial blood vessel, the stent comprising a flow-shaping member including a flow-facing surface that protrudes from an inner surface of the stent and is configured to control at least one of the direction, velocity and secondary flow characteristics of the blood flow within the aneurysm, wherein the stent comprises a series of axially spaced-apart annular struts in which adjacent struts are joined by axially extending links, and the flow-shaping surface is provided by a surface of at least one strut.

**2**. An intravascular stent for treatment of an aneurysm in a vessel wall of a cranial blood vessel, the stent comprising a flow-shaping member including a flow-facing surface that protrudes from an inner surface of the stent and is configured to control at least one of the direction, velocity and secondary flow characteristics of the blood flow within the aneurysm, wherein the stent comprises a plurality of struts arranged to form a cylindrical body, and wherein the flow-shaping member comprises a vane protruding from an inner surface of the stent.

**3**. The stent of claim **2** wherein the stent is configured to be disposed in the vessel so that the flow-shaping member extends at least partially across the opening while permitting substantially unobstructed blood flow into the aneurysm.

**4**. The stent of claim **2** wherein the stent is configured to be disposed in the vessel so that the flow-shaping member is disposed in the vessel at a location upstream of the opening.

**5**. The stent of claim **2** wherein the flow-shaping member protrudes inward from the inner surface of the stent so that the flow-facing surface extends in a non-normal direction relative to the inner surface of the stent.

**6**. An intravascular stent for treatment of an aneurysm in a vessel wall of a cranial blood vessel, the stent comprising a flow-shaping member including a flow-facing surface that protrudes from an inner surface of the stent and is configured to control at least one of the direction, velocity and secondary flow characteristics of the blood flow within the aneurysm, wherein the flow-facing surface is disposed at an acute deflection angle that is measured relative to the inner surface of the stent.

**7**. The stent of claim **6** wherein the deflection angle is in the range of 2 degrees to 60 degrees.

**8**. The stent of claim **6** wherein the deflection angle is in the range of 3 degrees to 30 degrees.

**9**. The stent of claim **6** wherein the deflection angle is in the range of 4 degrees to 15 degrees.

**10**. The stent of claim **6** wherein the deflection angle of the flow-facing surface is configured to divert at least a portion of the blood flow toward an axial centerline of the stent.

**11**. The stent of claim **6** wherein the deflection angle of the flow-facing surface is configured to divert at least a portion of the blood flow in a direction tangential to an axial centerline of the stent.

**12**. The stent of claim **1** wherein the flow-shaping member has a generally elliptical cross section, the flow-shaping member being oriented so that the long axis of the elliptical cross section is angled relative to an inner surface of the stent.

**13**. The stent of claim **2** wherein the flow-shaping member has a generally rectangular cross section, the flow-shaping member being oriented so that the long axis of the rectangular cross section is angled relative to an inner surface of the stent.

**14**. The stent of claim **2** wherein the stent includes two vanes, the vanes being elongated and each including a first portion aligned with an axial direction of the vessel, and a second portion angled relative to the first portion.

**15**. The stent of claim **14** wherein the second portion extends in a circumferential direction of the stent.

**16**. The stent of claim **14** wherein the second portion extends in a radial direction of the stent.

**17**. The stent of claim **14** wherein the two vanes are arranged so that a second portion of the first strut is disposed within the opening, and the second portion of the second strut overlies the first portion of the first strut.

**18**. The stent of claim **14** wherein the two vanes are arranged so that the respective first portions are parallel to an axial direction of the strut, and the respective second portions are diverging.

**19**. The stent of claim **1** wherein the flow-facing surface of each annular strut is disposed at an acute deflection angle that is measured relative to the inner surface of the stent.

**20**. The stent of claim **19** wherein the deflection angle varies about a circumference of an annular strut.

**21**. The stent of claim **19** wherein a first portion of one of the annular struts has a first deflection angle, a second portion of the one of the annular struts has a second deflection angle, and the first deflection angle is different from the second deflection angle.

**22**. The stent of claim **21** wherein the first deflection angle is orthogonal to the second deflection angle.

**23**. The stent of claim **21** wherein the first deflection angle is an acute angle, and the second deflection angle is zero.

**24**. The stent of claim **21** wherein the first and second portions are diametrically opposed.

**25**. The stent of claim **1** wherein the flow-facing surface is configured to direct flow in a first direction, and the stent further comprises a second flow-shaping member including a second flow-facing surface configured to direct flow in a second direction that is different from the first direction.

**26**. The stent of claim **25** wherein the flow-shaping members have the same shape.

**27**. The stent of claim **25** wherein the flow-shaping members have different shapes.

**28**. The stent of claim **25** wherein the first direction is orthogonal to the second direction.

**29**. The stent of claim **25** wherein the first direction includes a flow-direction component in a first axial direction of the stent, and the second direction includes a flow-direction component in a direction opposed to the first axial direction of the stent.

**30**. The stent of claim **1** wherein the stent includes a strut having a generally elliptical cross section, the long axis of the elliptical cross section being angled relative to a longitudinal axis of the stent so that the strut protrudes into the flow, the strut extending axially along a helical path, the helical path having a helix angle of greater than 60 degrees.

**31**. The stent of claim **2** comprising a vane including a flow-facing surface that protrudes from an inner surface of the stent and is configured to disrupt laminar blood flow within the stent.

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